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Soft contact lens designs for orthokeratology

Ulrich Wildenmann
Pacific University

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Soft Contact Lens Designs for Orthokeratology

Pacific University
College of Optometry
Forest Grove, Oregon, U.S.A.

Study Investigators:

Ulrich Wildenmann

Patrick Caroline, F.A.A.O.
Associate Professor of Optometry

Matthew Lampa, O.D., F.A.A.O.
Assistant Professor of Optometry

Beth Kinoshita, O.D., F.A.A.O.
Assistant Professor of Optometry

Mark Andre, F.A.A.O.
Associate Professor of Optometry

Jennifer Smythe, O.D., M.S., F.A.A.O.
Professor of Optometry

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Signature Page

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Student:

Ulrich Wildenmann

Approved by:

Patrick Caroline, F.A.A.O.

Matthew Lampa, O.D., F.A.A.O.

Beth Kinoshita, O.D., F.A.A.O.

Mark Andre, F.A.A.O.

Jennifer Smythe, O.D., M.S., F.A.A.O.

Vita

Ulrich Wildenmann
Noettingestr.32
76307 Karlsbad/ Germany
E-mail: ulrich.wildenmann@gmx.net

July 24, 1981 **Born – Karlsruhe, Germany**

Education

2005-2008 Pacific University, College of Optometry,
Forest Grove, Oregon U.S.A.
(in association with the University of Applied Sciences Aalen,
Aalen, Baden-Wuerttemberg Germany)

2003-2008 University of Applied Sciences Aalen,
Aalen, Baden-Wuerttemberg Germany
Areas of study: Optometry and auditory disabilities
Major: International optometry

2002-2003 Grammar School, Pforzheim, Germany
Degree awarded: University entrance diploma

1998-2001 Vocational School, Bruchsal, Germany, Optometry program
Degree awarded: Certified optician

Apprenticeship

1998-2001 Pientka der Augenoptiker, Lothar Pientka, proprietor,
Ettlingen, Germany
Degree awarded: Certificate of apprenticeship

Professional Experience

2005-2006 Optometric Assistant, Tualatin Eye Associates,
Craig E. Bowen OD,
Optometric Physician, Portland, Oregon U.S.A.

Community service

2001-2002 Orderly, Deaconess Hospital, Karlsruhe, Germany, Eye Clinic

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Chapter 1

Introduction I

1.1 -- History of Soft Contact Lenses

1.1 -- History of Soft Contact Lenses

In the year 1961, Professor Otto Wichterle and Drahoslav Lim developed the first soft contact lens material in Prague Czechoslovakia. This material was transparent, absorbed approximately 40 percent water and had good mechanical properties. The material was a cross-linking gel with the name "2-hydroxyethylmethacrylate" (pHEMA). This milestone in contact lens evolution was published in *New Scientist* in January1962.[1] Wichterle and Lim reported that certain hydrogels could be successfully used for the manufacture of contact lenses.[2] In 1964 the first soft contact lens "SPOFA-Lens" was introduced to the world market. However there were still many problems to be solved due to of the variation in optical quality, power and lens thickness. The wearing time of these first lenses was limited to eight hours because of the hazard of corneal edema. Despite the issues the Czechoslovakian lenses were sold around the world by the end of 1965. Many hospitals and institutions were interested in experimenting with this brand new soft contact lens material.[1] Many of the early high-water content lenses presented difficulties such as fragility and poor reproducibility.[2]
In 1971 Bausch & Lomb received Federal Drug Administration (FDA) approval for their "SOFLENS". Additionally, in 1976 the first soft, toric contact lens was FDA approved. The first manufacturers of these lenses were Weicon with their "Toric Lens" and Hydron with their "Rx Toric Lens".[1]

In the 1970s, scientific research proved that HEMA soft contact lenses could cause edema, vascularisation, corneal staining and giant papillary conjunctivitis (GPC). Through the 1980s a new generation of high-water content contact lenses was introduced to the international market. This new generation of soft contact lenses created the need for a regular replacement.[2]

In 1981 the FDA approval for extended-wear soft contact lenses was granted. One year later, the first disposal lens "Danalens" was manufactured and introduced to the Danish market. Vistakon manufactured the first weekly and daily lens. The weekly disposal lens "Acuvue" was introduced to the market in 1988. Seven years later, in 1995, the daily disposal lens with the name "1 Day Acuvue" followed. After the mid-1990s a new generation of soft contact lens material termed silicone hydrogel was introduced. The introduction of the "Focus Night & Day" in 1998 by CIBA Vision marked the beginning of a decline in the use of traditional hydrogel contact lenses.[1,2]

For almost two decades traditional hydrogel-based soft contact lenses drove research and the consumer market. It took until the late 1970s for a new process to be developed using silicone moieties.

In the late 1970s, initial studies were published proving that the addition of silicone moieties could improve the oxygen and carbon dioxide transmission properties of contact lenses.[3] A patent was issued to the Toyo Contact Lens Company in 1979 for a soft contact lens which had excellent oxygen permeability and low water content, allowing the lens to be worn over extended periods. Over the next two decades the progress in developing this new type of contact lens material was limited. The aim was to design a material with high oxygen permeability, good wettability, improved flexibility, optical clarity and deposit resistance. The difficulty was to find a material which combined the elements of silicone rubber with those of hydrogel-forming monomer such as HEMA (2-hydroxyethyl methacrylate) to get a co-polymer with the advantages of both.[4] The most unpleasant physiologic characteristic of silicone moieties is its non-wetting property and its ability to adsorb lipid and protein from the tear film.[3] The solution was the combination of HEMA and a monomer called TRIS (3-[tris(trimethylsilyloxy)-silyl]propyl methacrylate) which was successfully used in the preparation of rigid gas permeable lens materials.[4]

A significant development in the history of silicone hydrogel contact lenses was when CIBA was issued a patent in 1996. This patent meant that for the first time that there was a real possibility to design a contact lens for extended wear that had an adequate oxygen permeability with ionic or hydraulic permeability, enabling the lens to move on the eye without harming corneal health.[4] Since the mid-1990s different types of silicone hydrogel contact lenses were introduced to the market. First Bausch & Lomb introduced its "Pure Vision" lens in 1998. Ciba Vision's "Focus Night & Day" lens followed three years later. CIBA Vision's contact lens was unique due to its extended wearing period of up to thirty days with decreased corneal swelling potential because of its higher oxygen permeability. All these silicone hydrogel contact lenses have excellent handling characteristics because of their stiffness. The disadvantage of a stiffer lens material compared to hydrogel lenses is the mechanical effect on the corneal tissue. This results in dryness[3] and lower protein absorption[5] due to reduced water content.[3] Still, there remained several problems to solve before achieving the optimal lens material. The increase of the silicone content has the advantage of optimal oxygen permeability, however, the wettability is decreased due to increases in lipid interaction and deposition. Manufacturers have found different ways to overcome this problem by creating differing kinds of surface treatments. For example, Bausch & Lomb, has focused on plasma oxidation while CIBA Vision has identified a special plasma coating.[4]

There is no doubt that there is still a huge interest in improving this important class of materials while minimizing current patient issues.[4] More and more eye care practitioners are using silicone hydrogel lenses successfully for correcting a wide range of regular and irregular refractive error.[3] There is a great deal of research available showing that there remains continuous improvement in the development of silicone hydrogel materials for contact lenses. In particular, one of these studies show that first generation silicone hydrogel material "lotrafilcon A" has a significantly greater affinity for acanthamoeba than the second generation of silicon hydrogel material "galyfilcon A".[6] Furthermore, published studies showing that there is a significant reduction of microbial keratitis have surfaced. Future studies will need to be developed using the next generation of silicone hydrogel contact lenses to address overall design, antibacterial capabilities and increased patient comfort.[3]

Chapter 2

Introduction II

2.1 -- What is Orthokeratology

In 1971 the International Orthokeratology section of the National Eye Research Foundation defined orthokeratology as the reduction, modification or elimination of refractive anomalies by the programmed application of contact lenses. Orthokeratology is also known as OK, ortho-k, corneal reshaping, corneal refractive therapy (CRT), and vision shaping treatment (VST). It is a technique to reshape the corneal curvature through the use of rigid contact lenses.[7]

Orthokeratology has undergone a renaissance since the early 1990s with important achievements in both research and clinical practice. Orthokeratology lenses have a special design which causes central epithelial thinning and mid-peripheral thickening to reduce myopia. The use of reverse geometry gas-permeable lenses is an effective way to correct low and moderate myopia through central corneal flattening. Studies show the initial changes in corneal curvature are recorded after only a short period of lens wear - in a few minutes. However, it takes approximately one to ten days to achieve stable results. The whole procedure is reversible with a low risk factor with reports of possible microbial keratitis and corneal staining. Through the improvements of the last decade, overnight orthokeratology has become a viable alternative to refractive surgery.[8]

2.2 -- History of Orthokeratology

In ancient times, the Chinese slept with sandbags on their eyes for the reduction of myopia creating the first step in the evolution of orthokeratology. Further progress was made in the late 19th Century in 1888, when Eugene Kalt, a French ophthalmologist, fitted keratoconic patients with glass scleral contact lenses which applied pressure against the corneal apex. With the introduction of a corneal lens made out of polymethyl methacrylate (PMMA) in the late 1940s, refractive errors treated by contact lenses usage began to be recognized.[7]

In the 1950s practitioners noticed that the keratometric readings and the refractive errors of their contact lens patients changed after years of contact lens wear, including reports of myopia reduction and progression. These conflicting reports were the reason eye care practitioners were deeply interested in the reshaping of the cornea caused by the use of contact lenses.[9]

In 1962, the Seventh Congress of the International Society of Contact Lens Specialists was held in Chicago, Illinois. At this meeting George Jessen described, for the first time, his "Orthofocus Techniques". He reported his "deliberate effort" to reshape the human cornea with rigid contact lenses.[9] Also, at this meeting, the word "Orthokeratology" was used for the first time by Newton K. Wesley, and was immediately adopted as the recognized term for this new procedure.[10]

The first paper about orthokeratology was presented at the Second World Contact Lens Congress one year later. The paper reported that corneal reshaping was dependent on the application of contact lenses. In 1964, Jose Barraquer published encouraging results with orthokeratology in the journal *Refraction-Experimental-Surgery*.[11]

From 1976 to 1978 Kern completed a series of clinical investigations related to the efficacy of daily wear contact lenses for orthokeratology. He used PMMA lenses with a large diameter and conventional design. In this three-year study he compared myopic subjects wearing lenses which were fitted flatter than the standard keratometric reading. Furthermore, in 1983, the *Berkeley Orthokeratology Study* was published by Polse concluding that orthokeratology seemed to be a safe procedure but had limited clinical effects. Lynn J. Coon from Pacific University completed a study in 1984 based on the Tabb's orthokeratology fitting technique which used manipulation of the optic zone diameter to achieve central corneal flattening.[7] In this study the lenses were fitted slightly steeper than flat K to reduce myopia without inducing with-the-rule astigmatism. He achieved good lens centration and a decline in corneal astigmatism.[12]

In the following years the technological developments significantly reduced the costs for computerized corneal topographical mapping devices. The early 1990s brought the introduction of the reverse geometry lens design by Wlodyga and Stoyan and was a milestone for the history of orthokeratology. The study described a new lens design which induced rapid changes in myopic error in days without any problems due to poor lens centration.[7]

In 1994, Carney published a unique review of the traditional orthokeratology fitting techniques. Three years later Mountford reviewed the studies of Kern, Coon and Polse confirming these studies are still the most important articles published in the field of orthokeratology.[10]

The first lens approved by the U.S. Food and Drug Administration (FDA) was the Paragon CRT contact lens in 2002. Another confirming report was published by Jacobson in 2005 at the Global Orthokeratology Symposium in Chicago, Illinois showing how significant orthokeratology already is. He estimated that more than 150,000 patients have been fitted successfully with orthokeratology. Further support of the acceptance of orthokeratology is its widespread use in eastern Asia.[7]

2.3 -- Fitting Procedures for Orthokeratology

Currently there are three different kinds of fitting philosophies which are available on the contact lens market: Paragon CRT, BE-System and DreamLens.

1 -- Paragon CRT (developed by Paragon/ FDA approved in 2002)

In 2002, the FDA approved the first overnight orthokeratology contact lens manufactured by Paragon Vision Sciences of Mesa, Arizona. This achievement was a milestone in the development of orthokeratology. Paragon now manufactures a basic 100 lens diagnostic set and an expanded 130 lens diagnostic set including additional lenses with flatter base curves. These sets free the practitioner from continually ordering individual trial lenses. The most important item of the Diagnostic Dispensing System is the Initial Lens Selection Slide Rule making it easier to find the appropriate lens for every individual patient. The selection of these lenses is only dependent on the flat K and the manifest refraction sphere; by using the slide rule and two measurements then initial diagnostic lens parameters can be selected. Furthermore, approximately 80 percent of the patients are satisfied with the treatment effect of the initial lens. Additionally, to optimize centration and edge lift, the practitioner can select another lens within the fitting set with different landing zone angle (LZA) or return zone depth (RZD) and the same base curve. After achieving an optimal fit, the final Paragon Corneal Refractive Therapy (CRT) lens can simply be ordered.[13]

2 -- BE-System (developed by Bausch & Lomb/ FDA approved in 2004)

The BE-System fitting philosophy is based on topographical data obtained on the corneal shape and sagittal height measures; however, different parameters are required versus the Paragon CRT lens. The recommended topographer for this system is the Medmont E 300. To select the ideal initial trial lens, the practitioner must insert the following data into the BE-System program: apical radius calculation, sagittal height or eccentricity, axial/tangential maps, subtractive/difference maps and the desired refractive change. The obtained E-value also provides a quick reference to the patient's potential success in orthokeratology. With all this data the program is able to calculate the closest diagnostic trial lens in the standard BE retainer set. Every BE system customer receives a trial lens set which includes 25 lenses. The accuracy of this data prevents numerous re-trials and therefore saves time, effort and money.

After a careful slit lamp evaluation and corneal topography the exact lens parameters are generated and can be readily ordered from the manufacturer.[14,15]

3 -- DreamLens (developed by Bausch & Lomb/ FDA approved in 2004)

The DreamLens system is based on topographical data using thousands of orthokeratology patients after overnight use. After the examination of the patient and explanation of the procedure the first topography measurements are taken with a Medmont topographer. The next step is to transfer the data into the program for lens calculation. Requested data includes the spectacle prescription, the amount of cylinder, the axis, visual acuity with the spectacle prescription and the corneal diameter. The most important parameter is the corneal diameter because it determines the resulting diameter of the DreamLens. All this data has to be attached to an e-mail and sent directly to the DreamLens distributor laboratory. The help desk then reviews the order to make sure that there are no further questions. Once the customized parameters are collected the lens will be fabricated and shipped to the practitioner.[16]

All the above philosophies are partially based on the collection of different data. Paragon offers the only dispensing system which requires just two basic findings (Ks and spectacle Rx) which simplifies the initial lens selection for the practitioner. All the other fitting philosophies described in this article are based on corneal topography data. Bausch & Lomb's BE-System consists of a 25 lens diagnostic set from which the practitioner selects an overnight trial to assess treatment position at the first-day follow-up. The DreamLens is completely dependent on corneal topography -- all measurements have to be sent to a distributor laboratory where trial lenses will be manufactured individually. Generally all manufacturers recommend the use of a corneal topographer for fitting orthokeratology contact lenses accurately.

2.4 -- Overnight Orthokeratology

Current research in orthokeratology has proven that reverse geometry lenses are able to correct moderate myopia in open eye and overnight wear efficiently. The first report on overnight orthokeratology was done by Mountford in 1997. Three years later another study was published by Nichols and associates. Since then numerous prospective clinical studies of orthokeratology related research have taken place.

In 2004, a noteworthy study was published about myopia control proving that there is a significant decrease of axial growth and vitreous chamber depth after corneal reshaping lens wear. Additionally Rah and colleagues compared overnight orthokeratology patients to refractive surgery patients with results showing no significant difference in the visual outcome of these two procedures. Many different lens designs have been introduced to the market in the last ten years and surprisingly all of these seem to have nearly the same outcomes in corneal reshaping.[7]

Furthermore, international studies are suggesting that there is a significant change after just ten minutes of open eye contact lens wear. Scientists estimate that approximately 80 percent of the refractive error is achieved after the first night of orthokeratology contact lens wear with an endpoint being reached in seven to ten days. Once the target refraction is reached daytime regression averages between 0.25 D and 0.75 D. That is the reason why practitioners tend to overcorrect the patient slightly (pseudo hyperopia). In some cases subjects have to wear their lenses only every third to forth night to retain the corneal refractive change.[7]

Several studies have shown that orthokeratology is a reversible procedure. Barr and co-workers found that almost 90 percent of corneal recovery occurs in the first three days of the discontinuation of lens wear. However, there were significant individual differences between each subject -- some recover close to the corneal baseline in only eight hours, and others need 72 hours to achieve the same result.[7]

Sometimes visual problems occur secondary to under- or over-correction and residual refractive astigmatism while some subjects complain of ghosting[7], glare[34] and difficulty seeing in low light levels. Furthermore, corneal staining is a common side effect after lens removal.[7]

A lot of research has been conducted on irregular astigmatism and higher-order aberrations,[7,17] such as coma post-orthokeratology treatment. All these symptoms are related to an increased pupil diameter and a higher amount of myopic correction.[18,19]
Corneal reshaping contact lenses can create spherical aberration caused by the annular zone of mid peripheral corneal steepening and the corneal change from a prolate to an oblate shape. Such spherical aberration can reduce low contrast visual acuity.[7] Even though all of these scientific outcomes are still controversial in their significance[20], there is no doubt that there are corneal astigmatism increases in many clinical orthokeratology cases.[21,17]

A potential clinical consequence of overnight orthokeratology lens wear is a corneal iron ring. Current findings suggest that tear exchange between the corneal surface and the back surface of the contact lens plays a major role in the development of the corneal iron ring.[22]

Over the last two decades, the orthokeratology procedure has proven to be a safe method for the temporary elimination of moderate myopia[23] with microbial keratitis as a rare complication associated with overnight orthokeratology lens wear.[35] Current research proves that microbial keratitis is less frequent in daily contact lens wear versus overnight.[7]

Another study looked at corneal infection rates in felines with orthokeratology lenses worn on a continual basis. The study's method involved inoculating the lenses worn by the felines with bacteria to determine whether or not the bacteria infected the cornea. Study results concluded that orthokeratology lenses in the presence of an intact cornea did not result in a corneal infection. Furthermore, corneal thinning associated with overnight orthokeratology did not make the cornea more susceptible to microbial keratitis.[24]

Additional studies have shown that corneal reshaping lenses thin the central epithelium, around 30 percent, possibly weakening the epithelial barrier against microbial infection. An interesting statistic shows that almost 90 percent of all patients with microbial keratitis are of Asian ethnicity.[7] An alternative explanation of corneal thinning is an increase in cell shedding from the epithelial surface. Scientists hypothesized that morphological restructuring of individual cells might be responsible for the short-term changes in epithelial thickness.[36]
Microbial keratitis and acanthmoeba keratitis may also be related to the use of tap water for rinsing lenses and cases. Studies have also shown that if a contaminated lens is placed on the eye shortly before sleep the risk of eye infection is heightened.[7]

Using overnight orthokeratology to reduce of higher amounts of astigmatism of < 4.00 D is still under investigation. In Switzerland and other countries researching orthokeratology, scientists are trying to develop a reverse geometry lens design which should better treat astigmatism. Furthermore, there is ongoing research on orthokeratology for hyperopic patients showing that corneal steepening is slower than corneal flattening in myopic orthokeratology.[7]

Many researchers agree that the corneal stroma plays a bigger role in corneal reshaping than previously expected.[7] Clinical results suggest that pressure applied to the central cornea caused by reshaping lenses may create corneal swelling when worn overnight.[25] Additionally, scientists believe that corneal reshaping has no impact on the endothelium, while anecdotal evidence suggests that the density of the corneal endothelium cells respond to orthokeratology treatment. In one long-term study, the endothelium showed no changes over a period of one year of overnight orthokeratology lens wear,[26] consistent with the thought that all corneal changes develop on the anterior corneal layers only.

2.5 -- Current Status of Orthokeratology

Today orthokeratology is an effective way to allow low myopic patients to have clear vision through the day by wearing lenses on an overnight basis.[7] In 2002, the U.S. Food and Drug Administration approved the first overnight orthokeratology lens manufactured by Paragon Vision Sciences.[8] The use of reverse geometry gas permeable lenses provides a rapid refractive change within minutes. Current research is proving that the central epithelium thins and the midperipheral epithelium thickens in the first four weeks of lens wear. Recovery to nearly baseline takes between one to three days with complete recovery taking approximately two weeks. Several studies are finding that there are still some issues in fitting orthokeratology lenses, the most common and reversible side effects being halos and corneal staining. Additionally, there is evidence for microbial keratitis, corneal ulcers and an asymptomatic corneal pigmentation ring as well as an increase in higher order aberrations. There is evidence that corneal reshaping contact lenses may be able to slow the axial growth of the eye. This important discovery gives the chance to slow down or even stop the progression of myopia in the near future.[27] Scientists are trying to develop a soft contact lens design and material which will provide the same orthokeratology effects as the common rigid lenses for the progression of myopia.

All in all, current orthokeratology designs and materials are providing an excellent reversible treatment for moderate myopia.[8] New goals in orthokeratology research are to improve lens design and lens material for the correction of astigmatism, hyperopia and presbyopia.[7] Additionally, many patients discontinue orthokeratology lens wear because of the intolerance of rigid contact lenses. If these problems are quickly resolved, orthokeratology will be a more reliable alternative to refractive surgery.

Chapter 3

Introduction III

3.1 -- Soft Contact Lenses for Orthokeratology

3.1 -- Soft Contact Lenses for Orthokeratology

Soft contact lenses in orthokeratology are still a new topic in optometry. With only a few articles published worldwide, preliminary results have been encouraging and a preview to the future of soft contact lenses in orthokeratology.

At the meeting of the American Academy of Optometry in 2003, Patrick Caroline, F.A.A.O., gave one of the first lectures about the corneal reshaping results of a patient who wore a silicone hydrogel lens inside-out for an extended period.[28] The patient, who was wearing Focus Night & Day lenses (CIBA Vision), came to the clinic at Pacific University with visual problems. His corneal topography indicated central flattening and mid-peripheral steepening caused by wearing the lenses inside-out for several weeks. However, there were no complaints of discomfort or excessive lens movement which would be expected with an everted soft contact lens. This surprising observation was the reason for the following Pacific University study.[29]

The purpose of the investigation was to examine the topographic effects of silicone hydrogel contact lenses worn in everted and non-everted configurations. Fourteen myopic subjects were fitted with -6.00 D Focus Night & Day (CIBA Vision) silicone hydrogel contact lenses. None of the subjects knew they were fitted with an everted and non-everted lens on their eyes. Afterwards the first comfort survey for each lens was made. The subjects slept with lenses in and returned for a follow-up visit after twelve hours. A second comfort survey was done before the lenses were removed. The results of both comfort surveys proved that there is absolutely no noticeable comfort difference in wearing silicone hydrogel contact lenses inside-out. All patients showed topographical changes on the eye with the everted lens similar to those noted in rigid lens corneal reshaping. This study proved there is potential to create a specific soft lens design as a possible alternative to rigid contact lens corneal reshaping.[29]

In another Pacific University study, an everted -10.00 D Night & Day lens (CIBA Vision) was fitted on an amblyopic eye. After ten hours of overnight wear the first topographical measurement was taken. The corneal topography showed little or no change at the center of the cornea. One week later the central apical power had flattened -1.37 D and a concentric zone of greater flattening appeared -- flattest spot was -4.50 D. At the four week follow-up visit, the apical power reached -3.12 D of corneal flattening and the midperipheral cornea had its flattest point at -6.75 D. The conclusion of this study was that significant topographical changes can be achieved through everted silicone hydogel lenses in only four weeks without any irritation of the cornea.[30]

An additional study was performed at Pacific University in which Focus Night & Day lenses (CIBA Vision) with powers of -10.00 D, -6.00 D, -0.25 D and +6.00 D were used. All lenses were worn for a period of 6.5 hours during the day and overnight. Additionally, two more custom soft contact lenses manufactured in Benz-G5X (hioxifilcon A), with the powers of -20.00 D and -30.00 D were also evaluated. After each wearing period there was a break to allow the cornea to return to baseline. Surprisingly the central flattening of the cornea was higher in the daily wear period. For example the -10.00 D everted lens produced -2.50 D of flattening during daily wear in comparison to -1.30 D of flattening during overnight wear. One more interesting result was that the higher minus powered everted lenses showed greater topographical changes than low-powered everted lenses. Additionally higher minus powered everted lenses were also found to induce a mid-peripheral ring of epithelial staining.[31]

A furher study examined eyelid pressure -- another important indication of corneal reshaping. The pressure profiles were compared between soft contact lenses worn inside-out and right-side-in. All minus lenses (-6.00 D, -10.00 D, -20.00 D, -30.00 D) had a low-pressure area (300 Pa) near the optic zone and a high pressure area (>800 Pa) in the mid-periphery. However, the +6.00 D lens showed a lower central pressure (≈550 Pa). This study proved that there is a dramatic contrast in the pressure profiles between the everted and non-everted lenses -- the higher the power of the everted lens, the greater the area of the central treatment zone.[32]

An interesting case report was published by a private practitioner in *Contact Lens Spectrum*. He wrote about a myopic patient (-7.00 D OU) who had worn his right silicone hydrogel lens inside-out for 30 or 60 days. His right cornea flattened through this period of time around 1.00 D. After dispensing a new pair of trial lenses his corneal curvature returned back to baseline after two weeks.[28]

A 2006 report used a highly myopic patient (-13.00 D) who was concerned with blurred vision on his left eye only. The patient was fitted with CSI-T (CIBA Vision) soft lenses around ten years previously. A careful slit lamp examination showed both lenses to move and center perfectly with a blink. After the removal of the lenses a corneal imprint was found, caused by inadvertently wearing the high minus lens inside-out. The corneal mapping showed that there was a slight ring pattern developing on the surface of the left eye. This case demonstrates that soft contact lenses could inadvertently be worn inside-out in a daily wear fashion without any complications.

The same article included one additional comfort survey about everted soft contact lens wear. Twelve subjects were fitted with -10.00 D silicone hydrogel contact lenses. They were fitted right-side-in on one eye and inside-out on the other. After five minutes subjects rated the lens comfort for both eyes. The difference between the two results was 1.3 on a scale from 0 to 10 with 0 representing poor comfort and 10 excellent comfort. Afterwards the subjects wore their lenses overnight and had the lens comfort measured immediately after awakening. Again, the deviation was not significant (0.2), proving that it is almost impossible to judge if a lens is everted or not by comfort only.[33]

Early research briefly outlined in this project has clearly demonstrated that significant corneal reshaping can be accomplished using soft contact lenses. However, the studies do not identify the optimal lens design to achieve selective orthokeratology addressing both patient comfort and improved centration. After our extensive review of existing research we developed a number of pilot studies designed to identify the best soft contact lens for orthokeratology treatment. The design we felt had the greatest potential was the reverse geometry lens and the Ortho Tool software was employed to create it. The findings of our pilot studies follow.

Chapter 4

Pilot Study A

4.1 -- Everted Silicone Hydrogel Contact Lenses Worn Over a Long Term Period

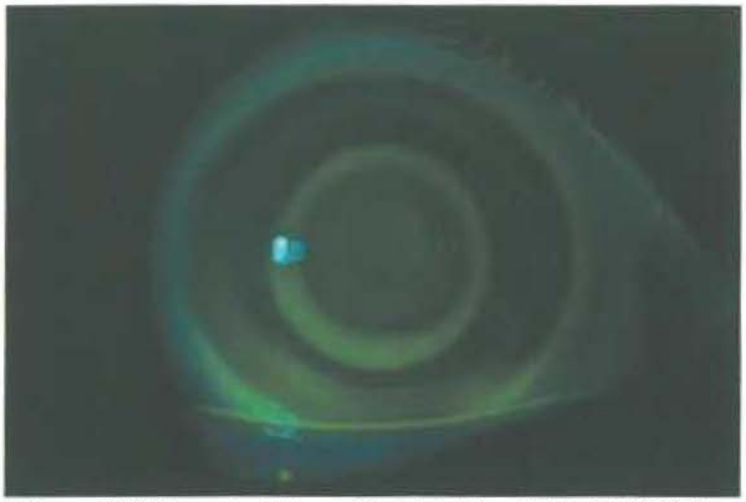
Start date:	March, 20th 2007	
Completion date:	December, 20th 2007	
Methods:	The subject was instructed to wear the lenses inside out overnight.	
Subject:	male/ 23 years old/ caucasian	
	Spectacle Rx OD:	-1.00 DS
	Spectacle Rx OS:	-1.00 DS
	Keratometry OD:	43.00/43.25 @ 0°/90°
	Keratometry OS:	43.00/43.25 @ 0°/90°
	Spectacle VA OD:	20/15
	Spectacle VA OS:	20/15
	Spectacle VA OU:	20/15
Contact Lens Parameters:	Lens:	Focus Night & Day
	Base curve:	8.4 mm
	Diameter:	13.8 mm
	Power:	-9.50 D
	Material:	lotrafilcon A
	Water content: 24%	
	Oxygen permeability (DK)	140
	Refractive index	1.43
Contact Lens Manufacturer:	CIBA Vision Corporation 11460 Johns Creek Parkway Duluth, Georgia 30097	

Conclusions:

- There is a limit to the minus power which is effective for treatment secondary to the creation of a central island with powers above -10.00 D.
- Low amounts of myopia (0.25 D to 1.00 D) can be corrected.
- Safe and effective over a long term period.

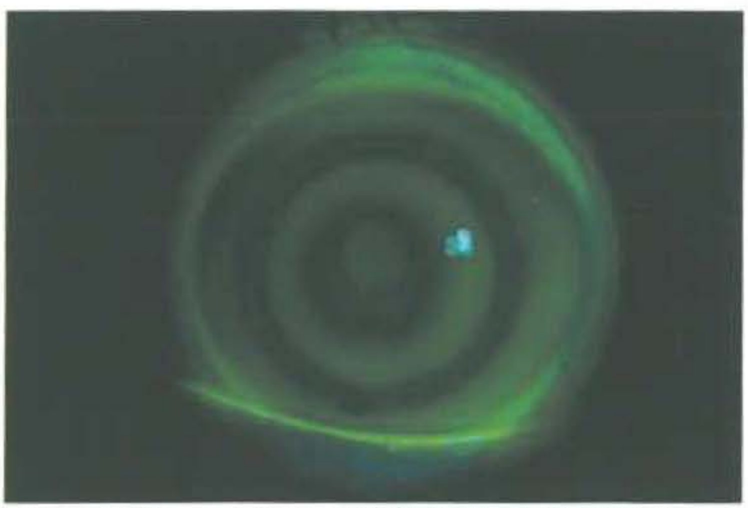
Advantages:	centers well, safe, comfortable, works efficiently
Disadvantage:	limited treatment zone and power

4.2 -- Fitted Focus Night & Day Lenses



(Figure 1) OD everted Focus Night & Day: 8.4/ -9.50/ 13.8

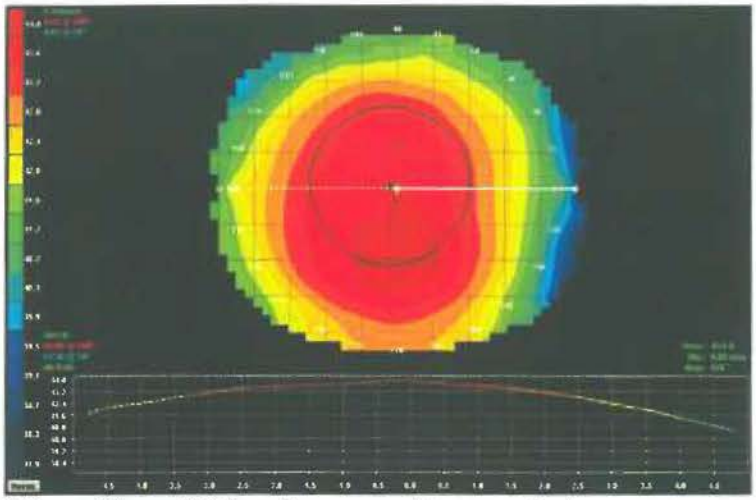
- well centered treatment zone with mid peripheral relief zone
- 0.25mm movement in primary gaze and 0.5mm movement in up gaze
- good limbal coverage
- no flutting
- no bubbles



(Figure 2) OS everted Focus Night & Day: 8.4/ -9.50/ 13.8

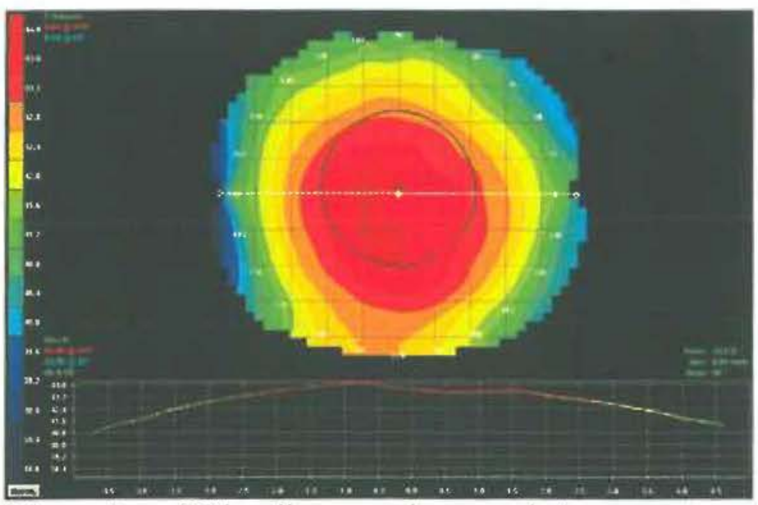
- well centered treatment zone with mid peripheral relief zone
- 0.25mm movement in primary gaze and 0.5mm movement in up gaze
- good limbal coverage
- no flutting
- no bubbles

4.3 -- Baseline Corneal Topography



(Figure 3) OD baseline corneal topography/
Sim K: 44.00/43.50 @ 109°/19°

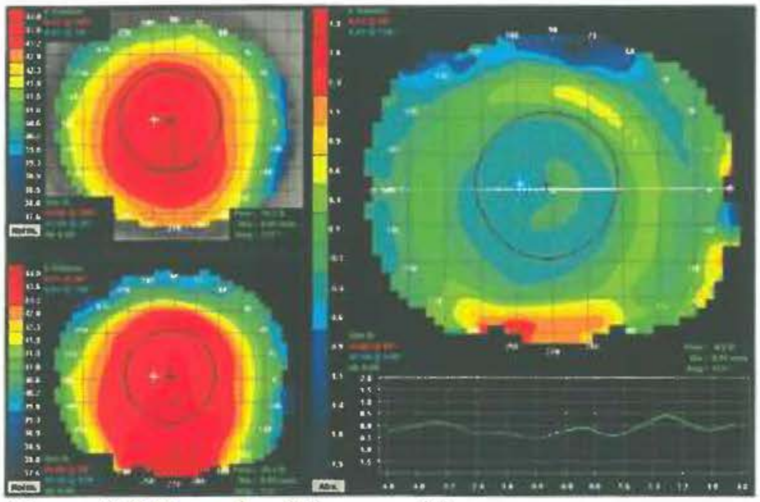
- mild/regular with the rule astigmatism



(Figure 4) OS baseline corneal topography/
Sim K: 43.80/43.70 @ 151°/61°

- mild/ regular with the rule astigmatism

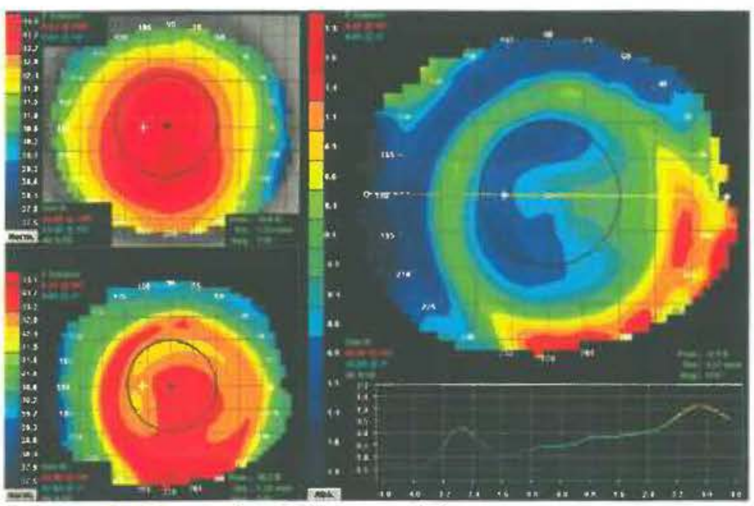
4.4 – One Day Follow-up Visit



(Figure 5) OD one day follow-up visit

- well centered treatment zone of central flattening

- maximum central flattening: -0.62 D
- unaided VA: 20/20

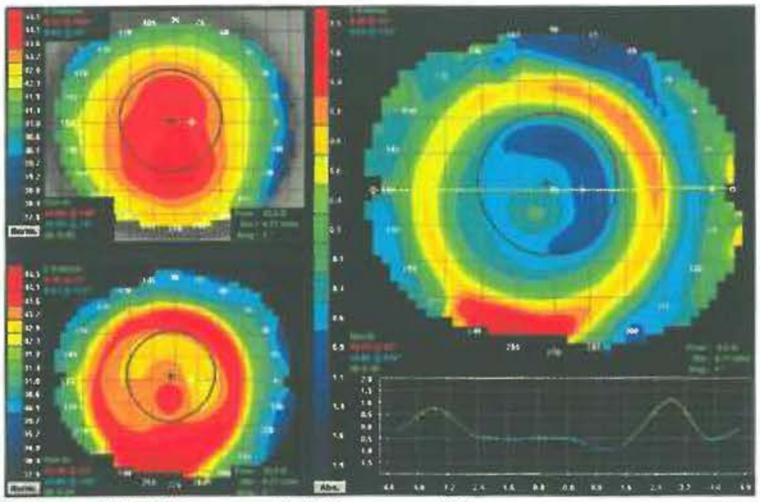


(Figure 6) OS one day follow-up visit

- well centered treatment zone of central flattening with greater flattening nasally

- maximum central flattening: -0.87 D
- unaided VA: 20/15

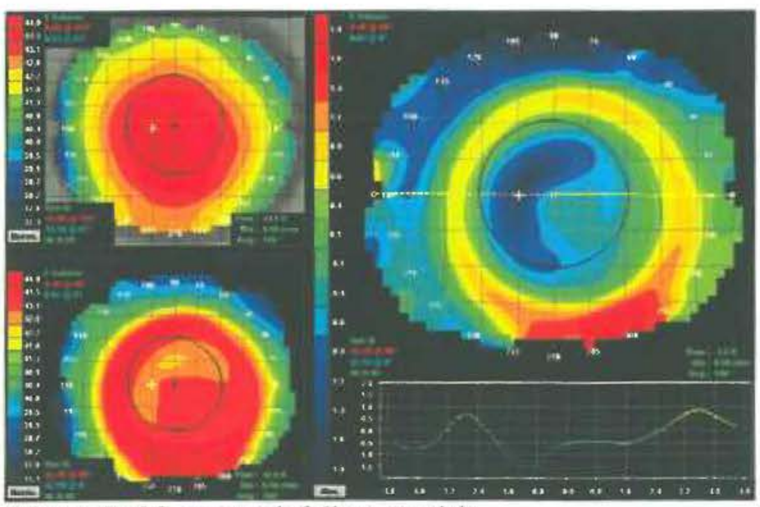
4.5 -- One Week Follow-up Visit



(Figure 7) OD one week follow-up visit

- well centered treatment zone of central flattening with greater flattening nasally

- maximum central flattening: -0.87 D
- unaided VA: 20/15

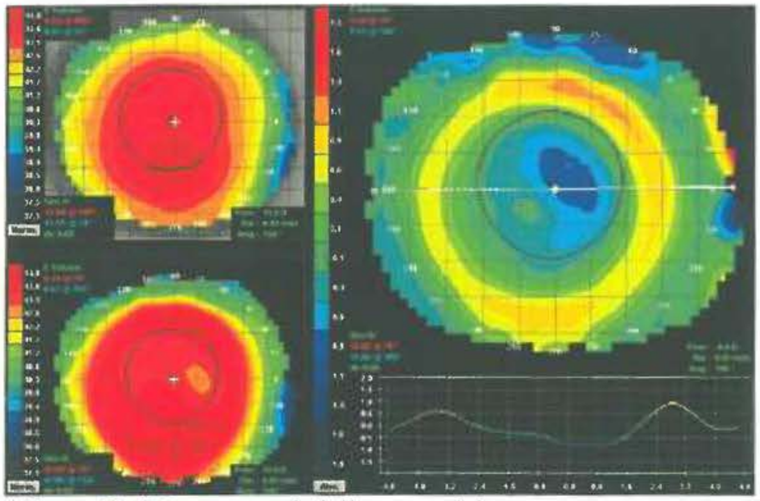


(Figure 8) OS one week follow-up visit

- well centered treatment zone of central flattening with greater flattening nasally

- maximum central flattening: -1.50 D
- unaided VA: 20/15

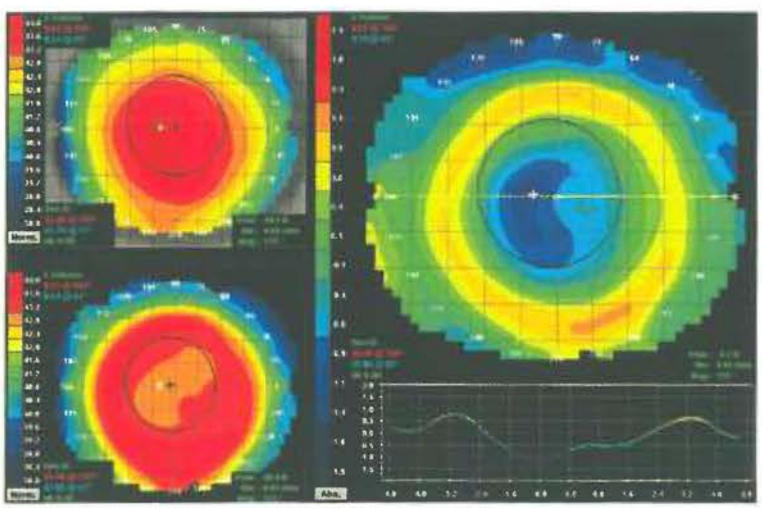
4.6 -- One Month Follow-up Visit



(Figure 9) OD one month follow-up visit

- well centered treatment zone of central flattening with greater flattening nasally

- maximum central flattening: -0.87 D
- unaided VA: 20/15

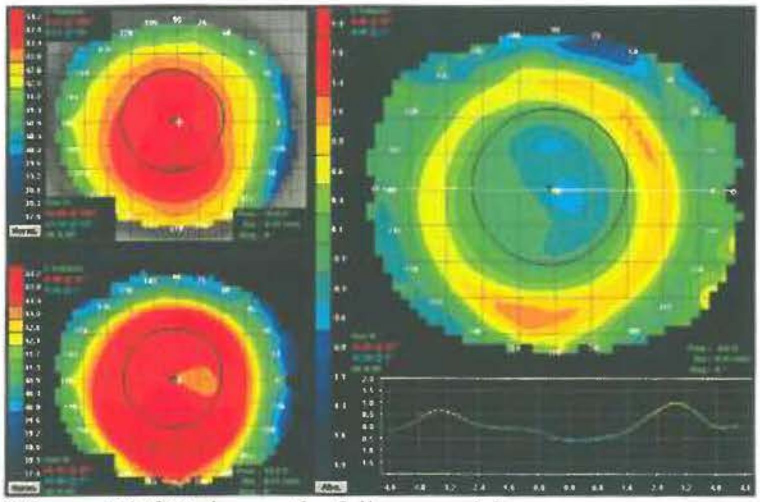


(Figure 10) OS one month follow-up visit

- well centered treatment zone of central flattening with greater flattening nasally

- maximum central flattening: -1.25 D
- unaided VA: 20/15

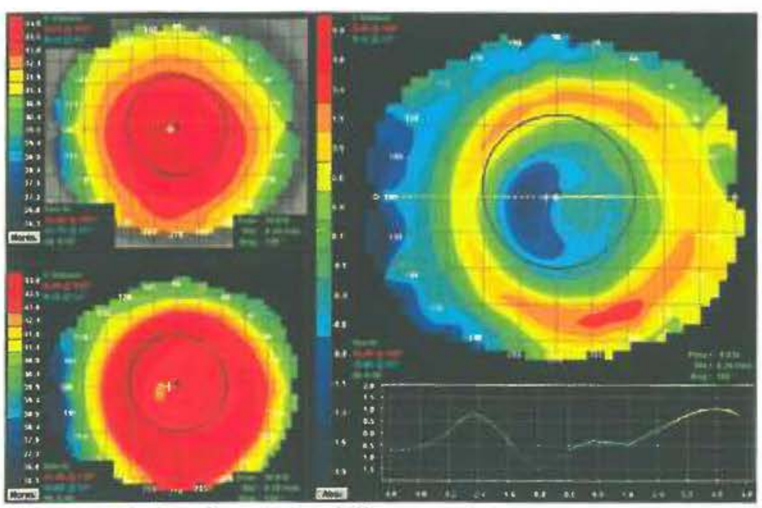
4.7 -- Six Months Follow-up Visit



(Figure 11) OD six months follow-up visit

- well centered treatment zone of central flattening with greater flattening nasally

- maximum central flattening: -0.62 D
- unaided VA: 20/15

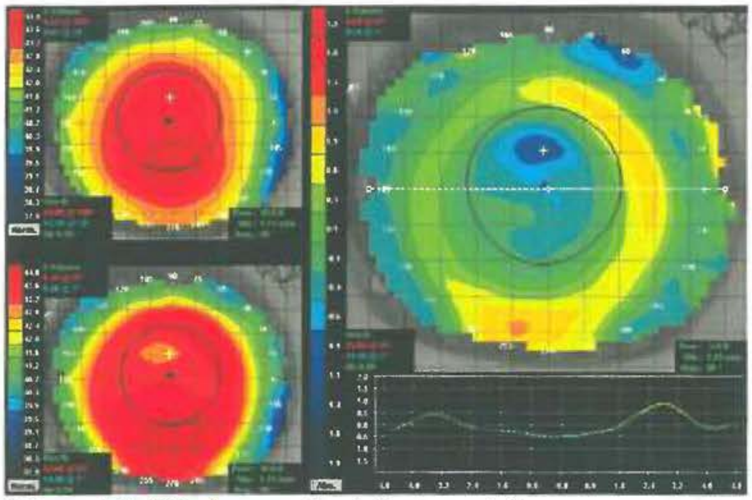


(Figure 12) OS six months follow-up visit

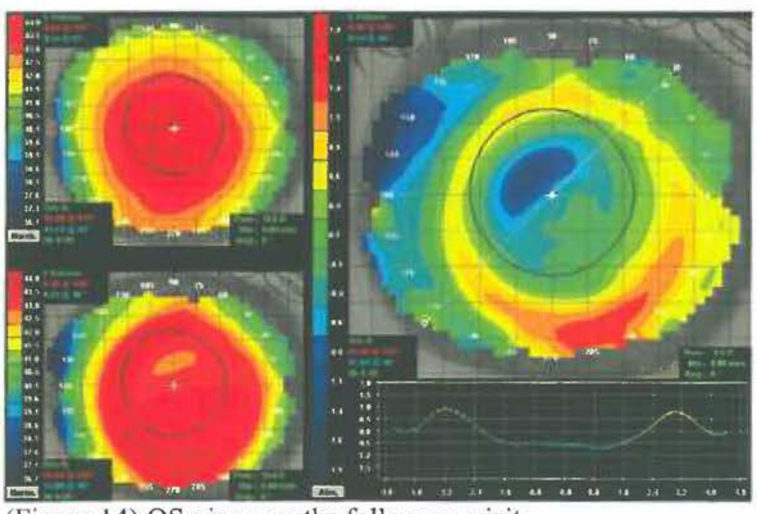
- well centered treatment zone of central flattening with greater flattening nasally

- maximum central flattening: -1.00 D
- unaided VA: 20/15

4.8 -- Nine Months Follow-up Visit


(Figure 13) OD nine months follow-up visit

- well centered treatment zone of central flattening with greater flattening at 11:00 o'clock
- maximum central flattening: -1.00 D
- unaided VA: 20/15


(Figure 14) OS nine months follow-up visit

- well centered treatment zone of central flattening with greater flattening at 10:00 o'clock
- maximum central flattening: -0.62 D
- unaided VA: 20/20

Chapter 5

Pilot Study B

5.1 -- Reverse Geometry Silicone Hydrogel Contact Lenses For Daily Wear

Start date:	May, 22nd 2007
Completion date:	June, 12th 2007

Methods: Eight hours of daily wear reverse geometry soft contact lenses for the reduction of myopia.

Subject: male/ 25 years old/ Caucasian

Spectacle Rx OD:	-3.25 DS
Spectacle Rx OS:	-3.25 DS
Keratometry OD:	44.00/44.50 @ 11°/101°
Keratometry OS:	44.00/44.50 @ 19°/109°
Spectacle VA OD:	20/15
Spectacle VA OS:	20/15
Spectacle VA OU:	20/15

Contact Lens Material: Experimental Silicone Hydrogel Material

Contact Lens Manufacturer: MedLens Innovation, Inc.
1325 Progress Drive
Front Royal, Virgina 22630

Conclusions:

- The reverse geometry soft lens design with an 8.50 central radius creates minimal topographical change of the cornea.
- The amount of eccentricity did not appear to be an important factor.

5.2 -- Summary

Results:

Lens 1 -- Spherical Lens Design

Parameters:	Power:	-10.00 D
	Base curve:	8.6
	Central thickness:	0.1
	Diameter:	14.2

Conclusion: The everted contact lens created a significant central island.

Lens 2 -- Reverse Geometry Spherical Lens Design

Parameters:	Power:	plano
	Base curve:	8.5
	Central thickness:	0.3
	Diameter:	14.2
	Reverse curve radius:	7.67

Conclusion: Spherical reverse curve contact lenses with an 8.50 central radius created a central island.

Lens 3 -- Aspheric Reverse Geometry Lens Design

Parameters:	Power:	plano
	Base curve:	8.5
	Eccentricity:	0.5
	Central thickness:	0.3
	Diameter:	14.2
	Reverse curve radius:	7.61

Conclusion: This reverse geometry contact lens design created minimal topographic change.

Lens 4 -- Aspheric Reverse Geometry Lens Design

Parameters:	Power:	plano
	Base curve:	8.5
	Eccentricity:	1.0
	Central thickness:	0.3
	Diameter:	14.2
	Reverse curve radius:	7.46

Conclusion: This contact lens created a central island.

Lens 5 -- Aspheric Reverse Geometry Lens Design

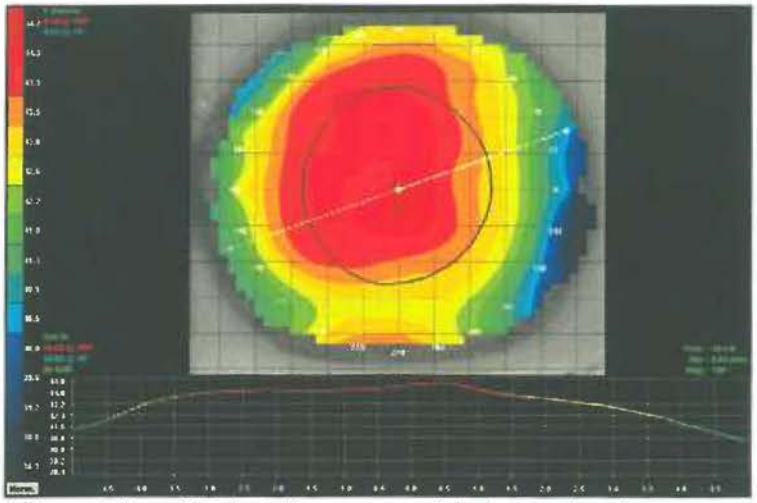
Parameters:	Power:	plano
	Base curve:	8.5
	Eccentricity:	1.5
	Central thickness:	0.3
	Diameter:	14.2
	Reverse curve radius:	7.24

Conclusion: The increasing amount of asphericity did not resolve the central island.

Conclusions -- Pilot Study B:

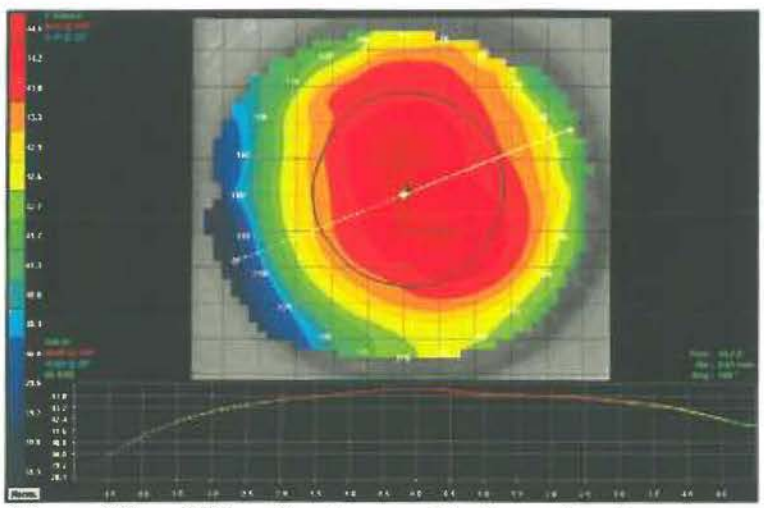
- The reverse geometry soft lens design with an 8.50 central radius creates minimal topographical change of the cornea.
- The amount of eccentricity did not appear to be an important factor.

5.3 -- Baseline Topographical Mappings



(Figure 15) OD baseline topographical mappings/
Sim K: 44.40/43.80 @ 109°/19°

- mild/regular with the rule astigmatism



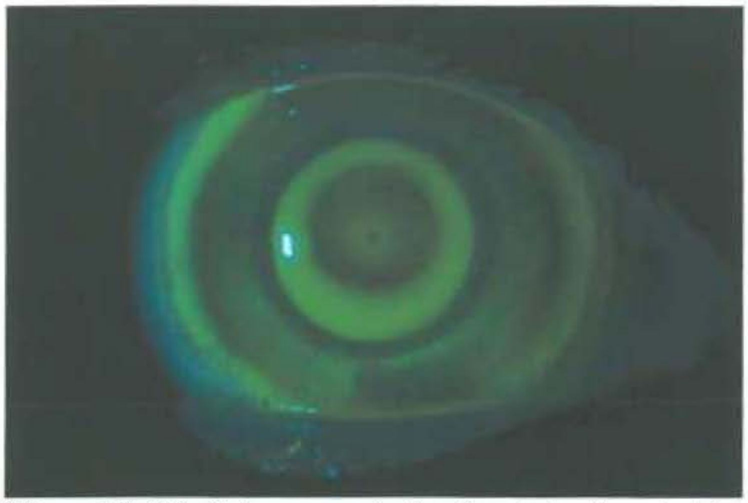
(Figure 16) OS baseline topographical mappings/
Sim K: 44.60/43.80 @ 112°/22°

- mild/regular with the rule astigmatism

5.4 -- Lens 1

OD:	Power:	-10.00 D
	Base curve:	8.6
	Central thickness:	0.1
	Diameter:	14.2

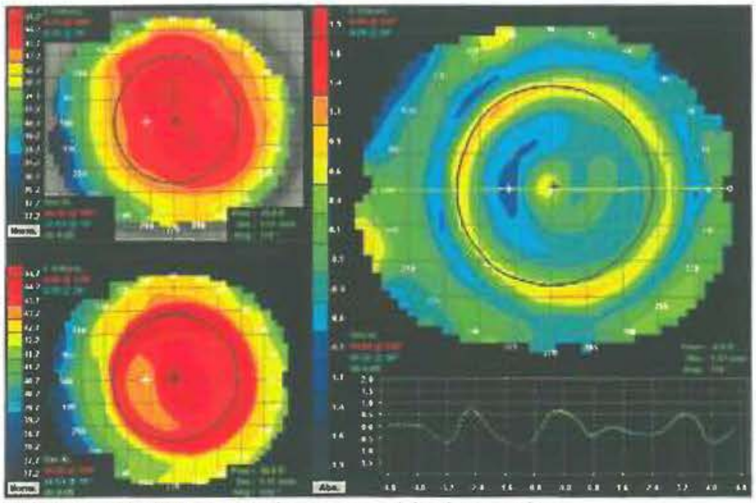
Spherical Lens Design



(Figure 17) OD slit lamp examination (everted soft contact lens)

- well centered treatment zone with mid peripheral relief zone
- 0.25mm movement in primary gaze and 0.5mm movement in up gaze
- good limbal coverage
- no flutting
- no bubbles

- lathe tool marks apparent centrally



(Figure 18) OD corneal topographical mapping

- topographical changes were created
- well centered treatment zone with ring of mid-peripheral steepening and area temporal to center of steepening within treatment zone with adjacent area of nasal flattening
- maximum central flattening: -0.87 D
- typical central island was created

Conclusion: The everted contact lens created a significant central island.

5.5 -- Lens 2

OD:	Power:	plano
	Base curve:	8.5
	Central thickness:	0.3
	Diameter:	14.2
	Reverse curve radius:	7.67
	Over refraction:	-3.25 D

Spherical Reverse Geometry Lens Design

EyeDeal Software & Design

OrthoTool 2000 Ver: 05.01.02 www.EyeDealSoftware.com

Fit Design

Practitioner: Patrick Caroline, FAAO **Patient:** Lens #1

Cornea Readings	Right	Left	Corneal Axis ID	Right	Left	Corneal Cross	Right	Left
1st K Reading	44.00		Flattest K	44.00		Flat K (mm)	7.67	
2nd K Reading	44.50		Steepest K	44.50		Steep K (mm)	7.58	
2nd K Meridian	90		Flat Axis	180		Delta K (diop)	0.50	
Eccentricity	0.40							
Refractive Error			**Minus Cylinder**			**Optical Cross (Vertex)**		
Sphere	-3.25		Sphere	-3.25		Flat Power	-3.25	
Cylinder			Cylinder			Steep Power	-3.25	
Axis			Axis			Delta Cyl		
Vertex Distance	12							
	Clear R Rx	Clear L Rx		Define Complex Corneas				

Considerations	Corneal Cylinder	Refractive Cylinder	Clinical Questions	Lens Suggestion	Residual Cylinder
Right Eye	With the Rule	#VALUE!		Std Sphere or Thin	
Left Eye					

Select Designs	Auto Fill	Base	Power	CT / e	Dia / BOZ	Rev	Int	Sec	PC	FOZ / ET
OrthoK CC	Copy to Lens Design Page	8.44	0.75	0.18	10.6	7.04	#N/A	#N/A	11.50	7.0
					6.0	1.00	0.50	0.50	0.30	0.14
OrthoK CC	Clear Lens Design Page									

	R Corneal Curves	Semi Diameter	L Corneal Curves	Semi Diameter
Apical Zone	44.00	3.0		3.0
Zone 2	43.25	4.0		4.0
Zone 3	42.00	5.0		5.0
Zone 4	41.00	6.0		6.0
Peripheral Zone	41.00	14.2		

Restore Default Values bradley

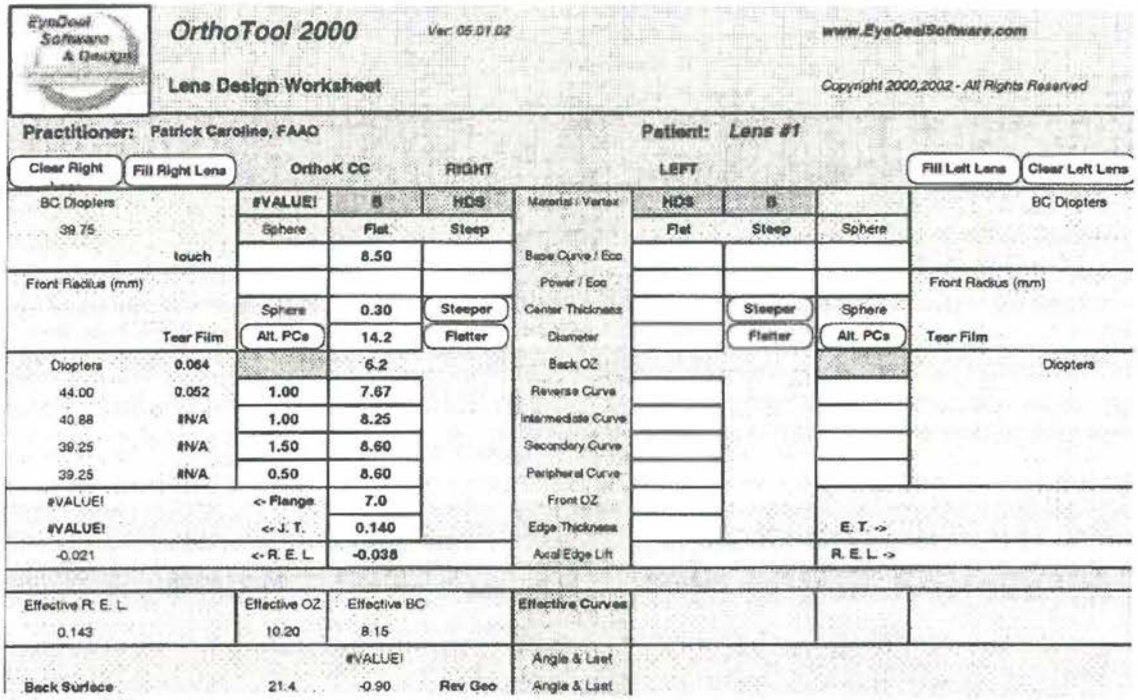
Define Complex Corneal Shapes Top of Form

Corneal topography maps can be used to describe the corneal curvature at various semi diameters when fitting lenses on keratoconus, post surgical and diseased eyes.

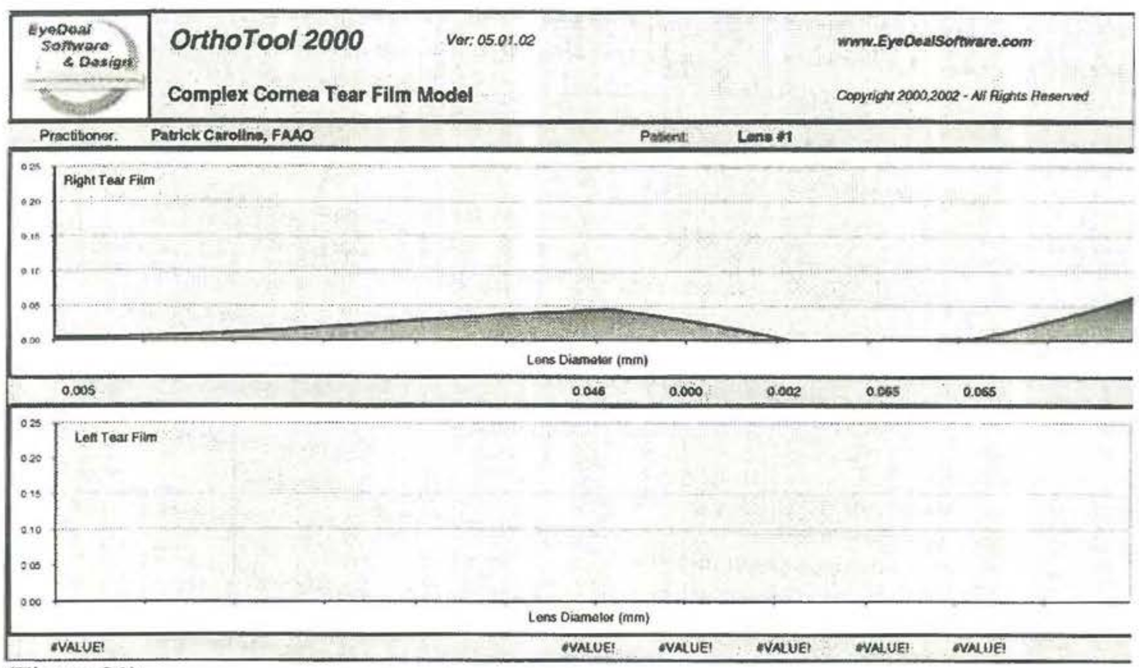
The lens specifications from the Lens Design worksheet will be compared to the shape described on this chart with the resulting alignment displayed as a Complex Tear Film.

1) Mark a point on the corneal map that suggests the apex or highest point on the cornea.
2) Draw a line on the map that best defines the flattest axis of symmetry.
3) Draw a line 90 degrees from the first line and note the axis.
4) Enter the central K readings and the secondary K axis noted in Step 3.
5) Estimate and enter the average K reading and the corresponding semi-diameters at 5 different points along your flat axis of symmetry.
6) To improve accuracy, enter the parameters of a known lens on the LENS DESIGN worksheet, compare the fluorescene pattern to the COMPLEX TEAR FILM and readjust your corneal model to match the stain pattern.

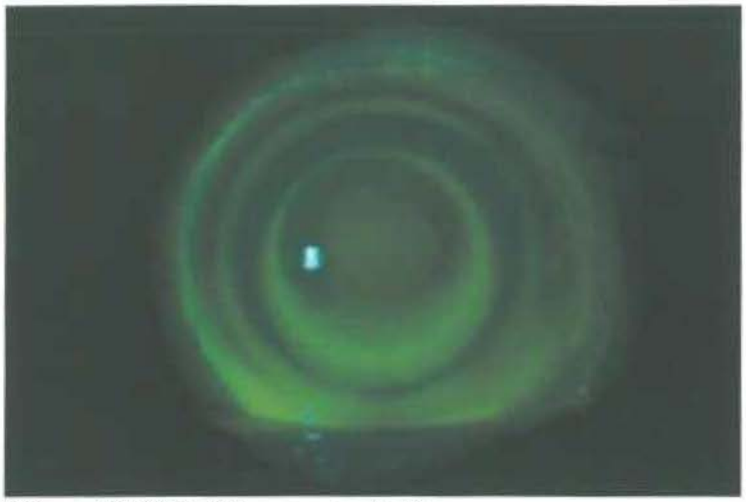
(Figure 19)



(Figure 20)



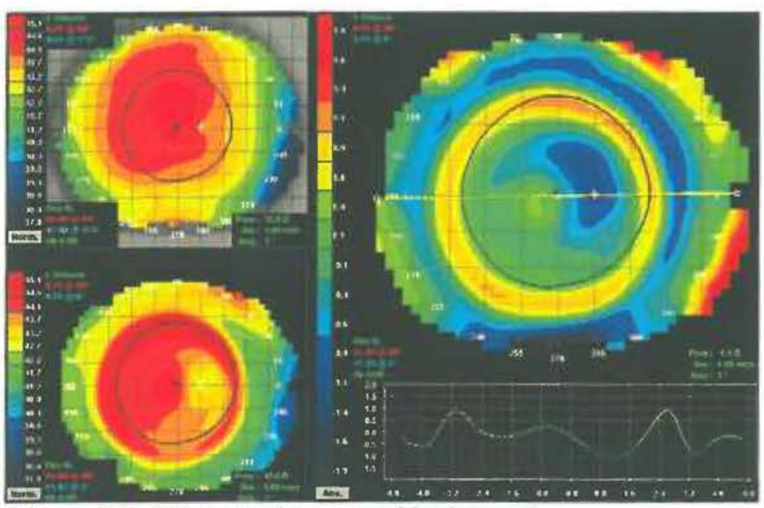
(Figure 21)



(Figure 22) OD slit lamp examination

Subjectively: blurry vision secondary to lens deposits

- well centered treatment zone with mid peripheral relief zone
- 0.25mm movement in primary gaze and 0.5mm movement in up gaze
- good limbal coverage
- no flutting
- no bubbles



(Figure 23) OD corneal topographical mapping

- topographical changes were created
- well centered treatment zone with ring of mid-peripheral steepening and area temporal to center of steepening within treatment zone with adjacent area of nasal flattening
- maximum central flattening: -1.12 D

Conclusions: Spherical reverse curve contact lenses with an 8.50 central radius created a central island.

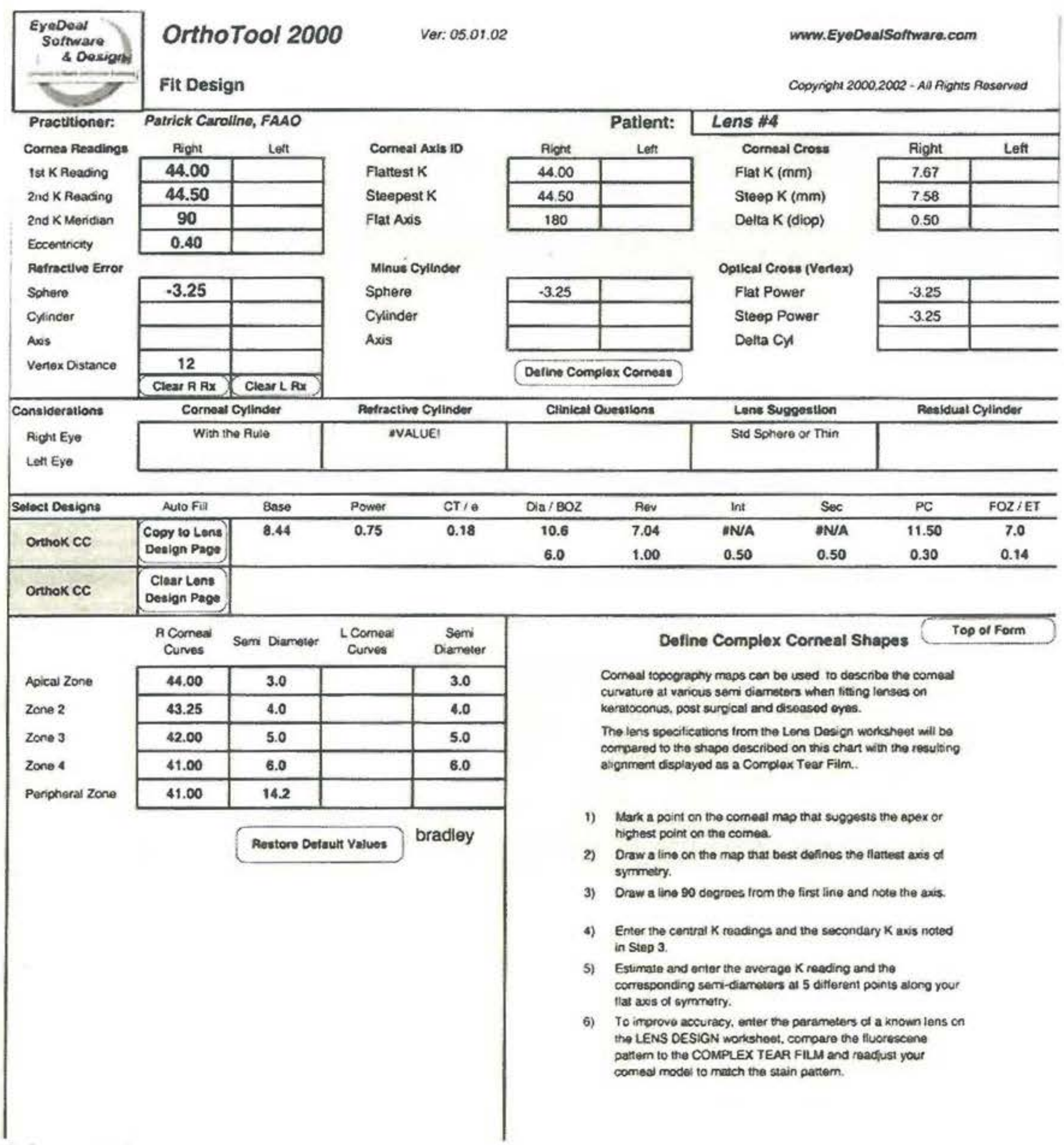
There are two options:

1) flatten the 8.50 central base curve radius
2) keep the 8.50 radius and make it aspherical

5.6 -- Lens 3

OD:	Power:	plano
	Base curve:	8.5
	Eccentricity:	0.5
	Central thickness:	0.3
	Diameter:	14.2
	Reverse curve radius:	7.61

Aspheric Reverse Geometry Lens Design



EyeDeal Software & Design

OrthoTool 2000 Ver: 05.01.02 www.EyeDealSoftware.com

Fit Design

Copyright 2000,2002 - All Rights Reserved

Practitioner: Patrick Caroline, FAAO Patient: Lens #4

Cornea Readings	Right	Left	Corneal Axis ID	Right	Left	Corneal Cross	Right	Left
1st K Reading	44.00		Flattest K	44.00		Flat K (mm)	7.67	
2nd K Reading	44.50		Steepest K	44.50		Steep K (mm)	7.58	
2nd K Meridian	90		Flat Axis	180		Delta K (diop)	0.50	
Eccentricity	0.40							
Refractive Error			Minus Cylinder			Optical Cross (Vertex)		
Sphere	-3.25		Sphere	-3.25		Flat Power	-3.25	
Cylinder			Cylinder			Steep Power	-3.25	
Axis			Axis			Delta Cyl		
Vertex Distance	12							

Clear R Rx Clear L Rx Define Complex Corneas

Considerations	Corneal Cylinder	Refractive Cylinder	Clinical Questions	Lens Suggestion	Residual Cylinder
Right Eye	With the Rule	#VALUE!		Std Sphere or Thin	
Left Eye					

Select Designs	Auto Fill	Base	Power	CT / e	Dia / BOZ	Rev	Int	Sec	PC	FOZ / ET
OrthoK CC	Copy to Lens Design Page	8.44	0.75	0.18	10.6	7.04	#N/A	#N/A	11.50	7.0
					6.0	1.00	0.50	0.50	0.30	0.14
OrthoK CC	Clear Lens Design Page									

	R Corneal Curves	Semi Diameter	L Corneal Curves	Semi Diameter
Apical Zone	44.00	3.0		3.0
Zone 2	43.25	4.0		4.0
Zone 3	42.00	5.0		5.0
Zone 4	41.00	6.0		6.0
Peripheral Zone	41.00	14.2		

Restore Default Values bradley

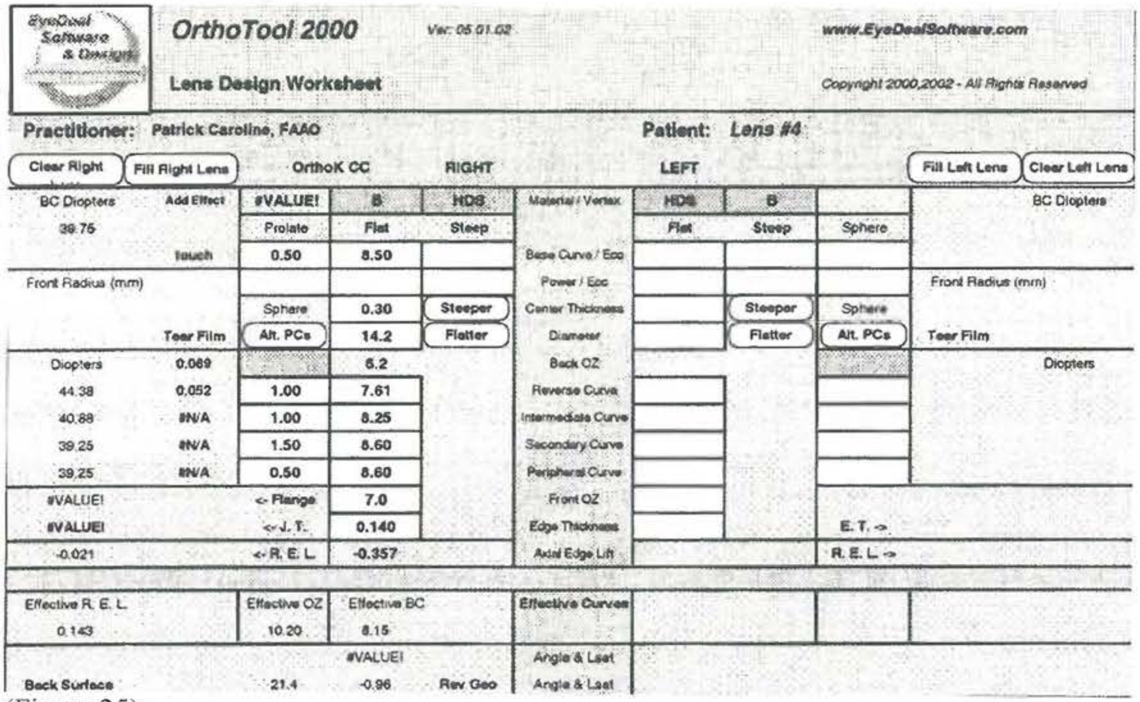
Define Complex Corneal Shapes Top of Form

Corneal topography maps can be used to describe the corneal curvature at various semi diameters when fitting lenses on keratoconus, post surgical and diseased eyes.

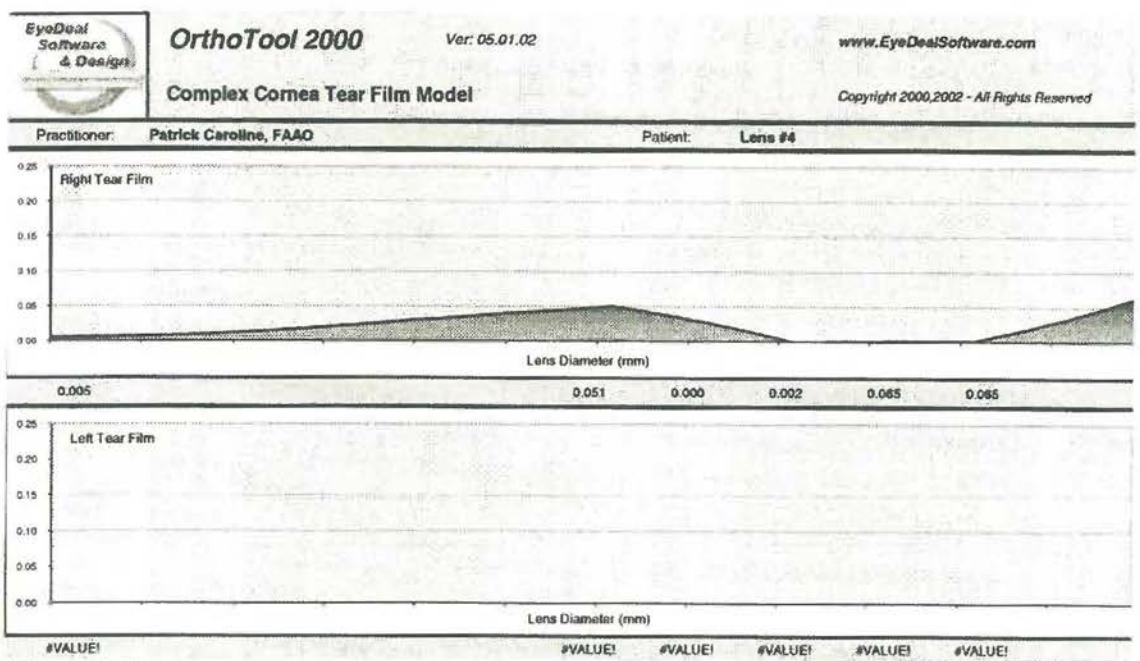
The lens specifications from the Lens Design worksheet will be compared to the shape described on this chart with the resulting alignment displayed as a Complex Tear Film..

1) Mark a point on the corneal map that suggests the apex or highest point on the cornea.
2) Draw a line on the map that best defines the flattest axis of symmetry.
3) Draw a line 90 degrees from the first line and note the axis.
4) Enter the central K readings and the secondary K axis noted in Step 3.
5) Estimate and enter the average K reading and the corresponding semi-diameters at 5 different points along your flat axis of symmetry.
6) To improve accuracy, enter the parameters of a known lens on the LENS DESIGN worksheet, compare the fluorescene pattern to the COMPLEX TEAR FILM and readjust your corneal model to match the stain pattern.

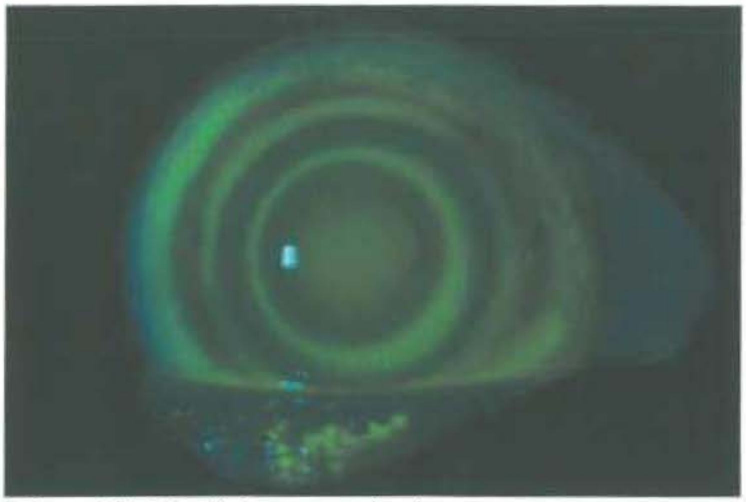
(Figure 24)



(Figure 25)

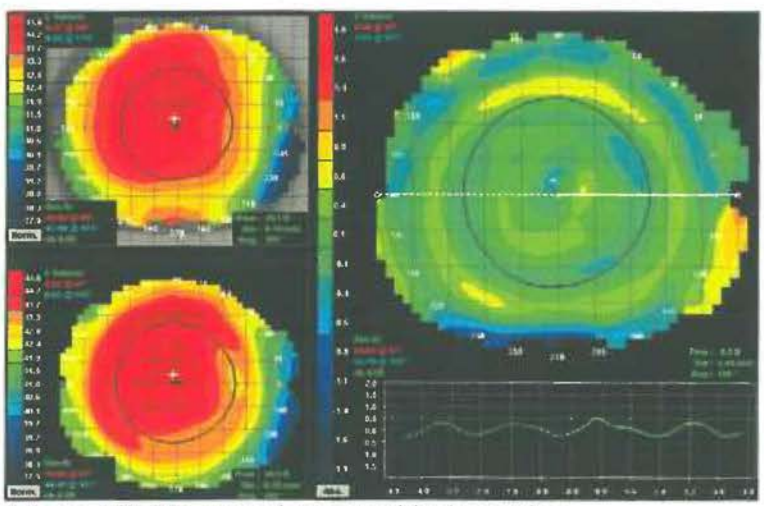


(Figure 26)



(Figure 27) OD slit lamp examination

- well centered treatment zone with mid peripheral relief zone
- 0.25mm movement in primary gaze and 0.5mm movement in up gaze
- good limbal coverage
- no flutting
- no bubbles



(Figure 28) OD corneal topographical mapping

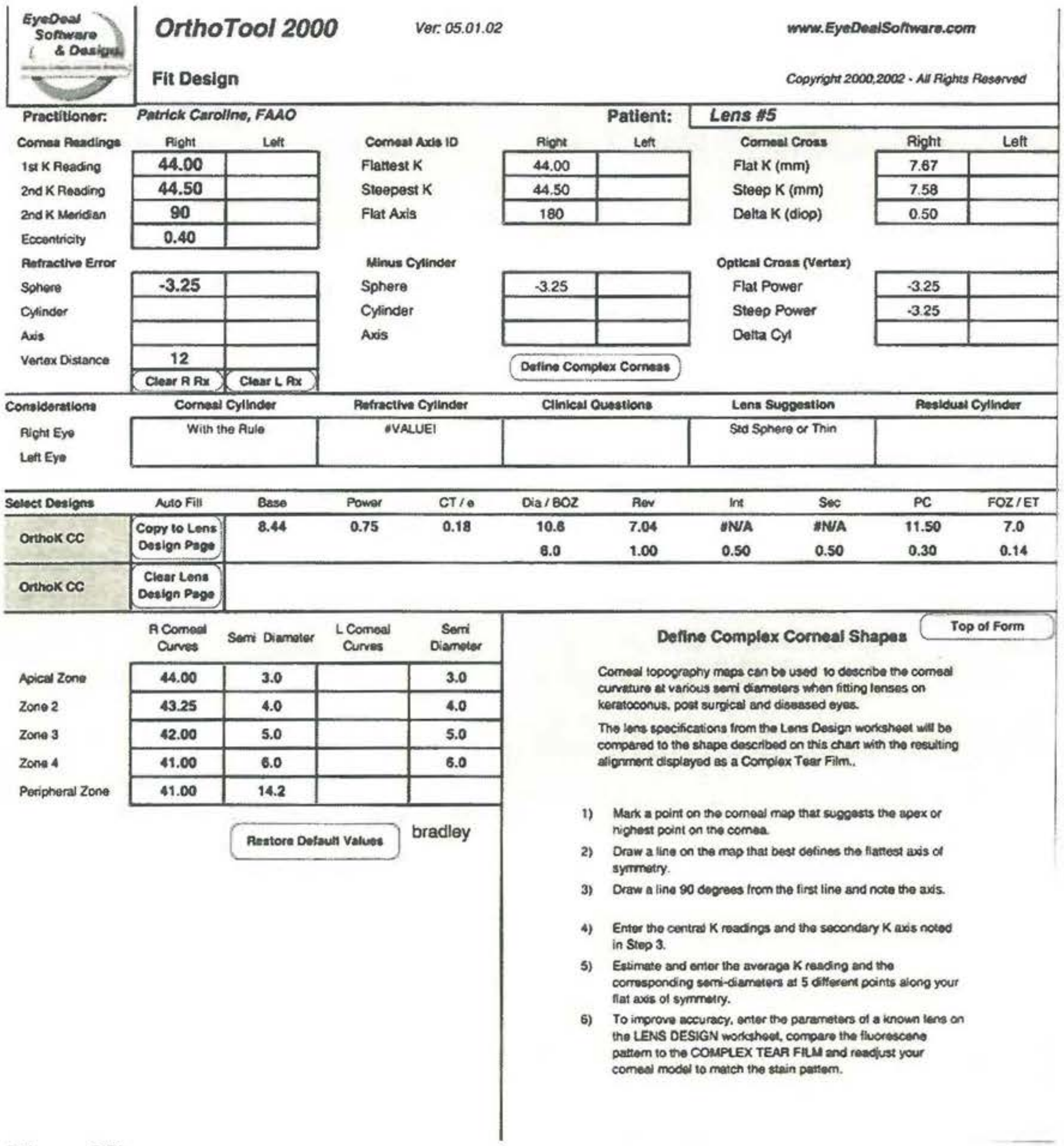
- insignificant topographical changes were created
- areas of central flattening and steepening with circumferential ring of steepening
- no over refraction
- maximum central flattening: -0.37 D

Conclusion: This reverse geometry contact lens design created minimal topographic change.

5.7 -- Lens 4

OS:	Power:	plano
	Base curve:	8.5
	Eccentricity:	1.0
	Central thickness:	0.3
	Diameter:	14.2
	Reverse curve radius:	7.46

Aspheric Reverse Geometry Lens Design



EyeDeal Software & Design

OrthoTool 2000 Ver: 05.01.02 www.EyeDealSoftware.com

Fit Design Copyright 2000,2002 - All Rights Reserved

Practitioner: Patrick Caroline, FAAO **Patient:** Lens #5

Cornea Readings	Right	Left	Corneal Axis ID	Right	Left	Corneal Cross	Right	Left
1st K Reading	44.00		Flattest K	44.00		Flat K (mm)	7.67	
2nd K Reading	44.50		Steepest K	44.50		Steep K (mm)	7.58	
2nd K Meridian	90		Flat Axis	180		Delta K (diop)	0.50	
Eccentricity	0.40							
Refractive Error			Minus Cylinder			Optical Cross (Vertex)		
Sphere	-3.25		Sphere	-3.25		Flat Power	-3.25	
Cylinder			Cylinder			Steep Power	-3.25	
Axis			Axis			Delta Cyl		
Vertex Distance	12							
	Clear R Rx	Clear L Rx		Define Complex Corneas				

Considerations	Corneal Cylinder	Refractive Cylinder	Clinical Questions	Lens Suggestion	Residual Cylinder
Right Eye	With the Rule	#VALUE!		Std Sphere or Thin	
Left Eye					

Select Designs	Auto Fill	Base	Power	CT / e	Dia / BOZ	Rev	Int	Sec	PC	FOZ / ET
OrthoK CC	Copy to Lens Design Page	8.44	0.75	0.18	10.6	7.04	#N/A	#N/A	11.50	7.0
					6.0	1.00	0.50	0.50	0.30	0.14
OrthoK CC	Clear Lens Design Page									

	R Corneal Curves	Semi Diameter	L Corneal Curves	Semi Diameter
Apical Zone	44.00	3.0		3.0
Zone 2	43.25	4.0		4.0
Zone 3	42.00	5.0		5.0
Zone 4	41.00	6.0		6.0
Peripheral Zone	41.00	14.2		

Restore Default Values bradley

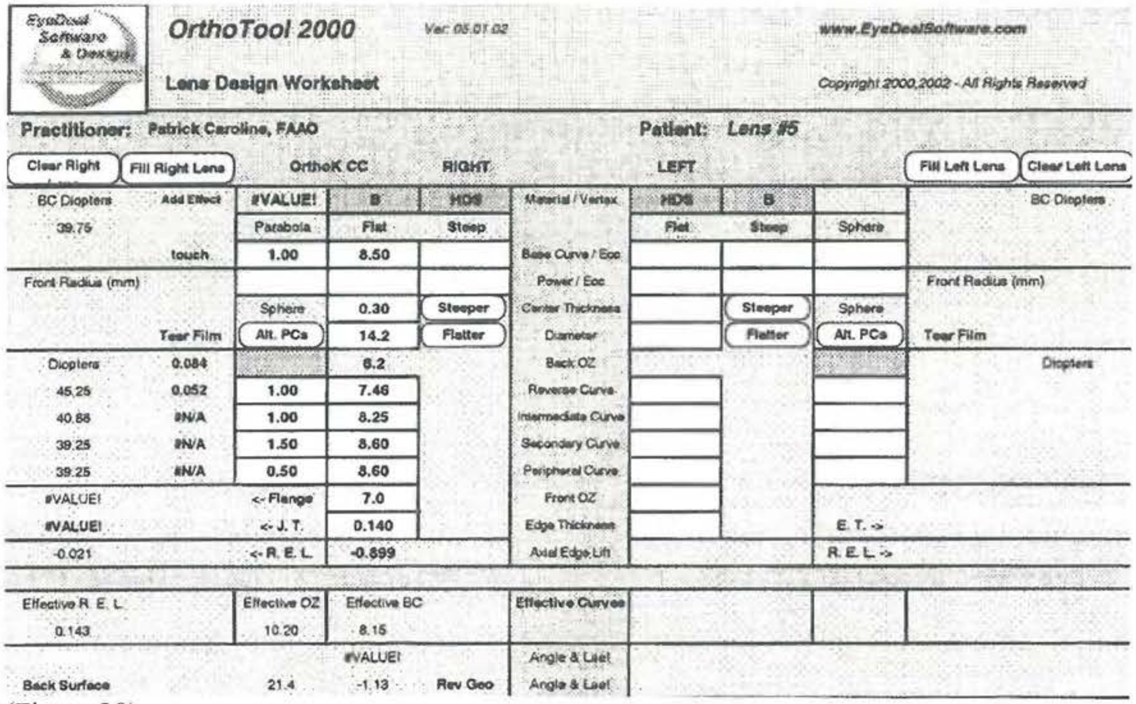
Define Complex Corneal Shapes Top of Form

Corneal topography maps can be used to describe the corneal curvature at various semi diameters when fitting lenses on keratoconus, post surgical and diseased eyes.

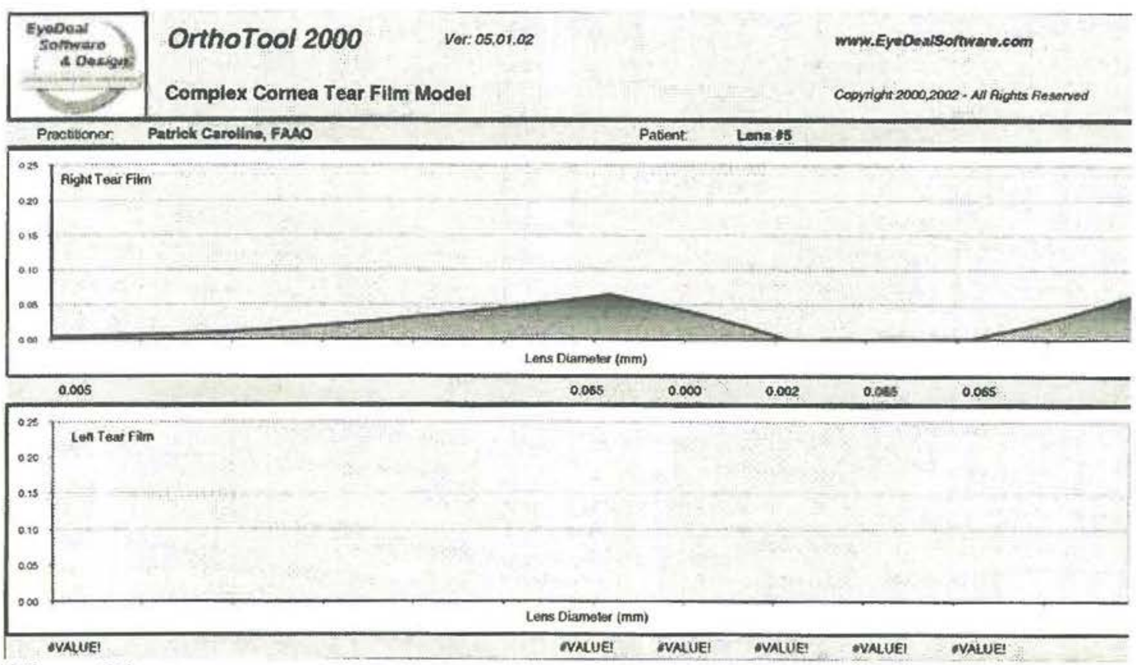
The lens specifications from the Lens Design worksheet will be compared to the shape described on this chart with the resulting alignment displayed as a Complex Tear Film.

1) Mark a point on the corneal map that suggests the apex or highest point on the cornea.
2) Draw a line on the map that best defines the flattest axis of symmetry.
3) Draw a line 90 degrees from the first line and note the axis.
4) Enter the central K readings and the secondary K axis noted in Step 3.
5) Estimate and enter the average K reading and the corresponding semi-diameters at 5 different points along your flat axis of symmetry.
6) To improve accuracy, enter the parameters of a known lens on the LENS DESIGN worksheet, compare the fluorescene pattern to the COMPLEX TEAR FILM and readjust your corneal model to match the stain pattern.

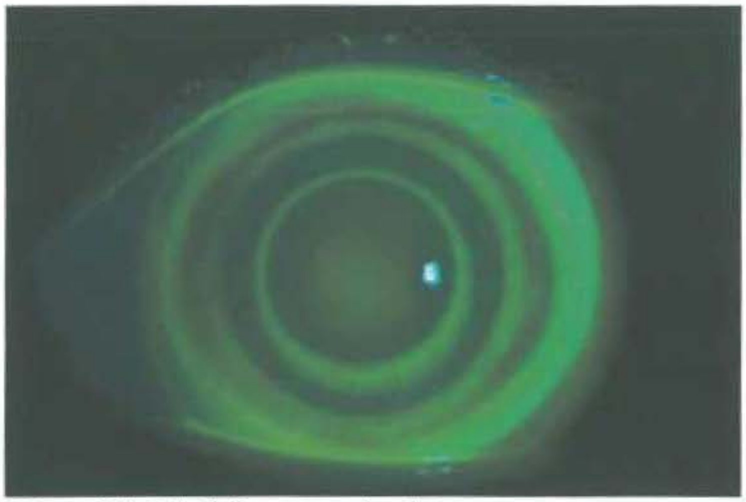
(Figure 29)



(Figure 30)

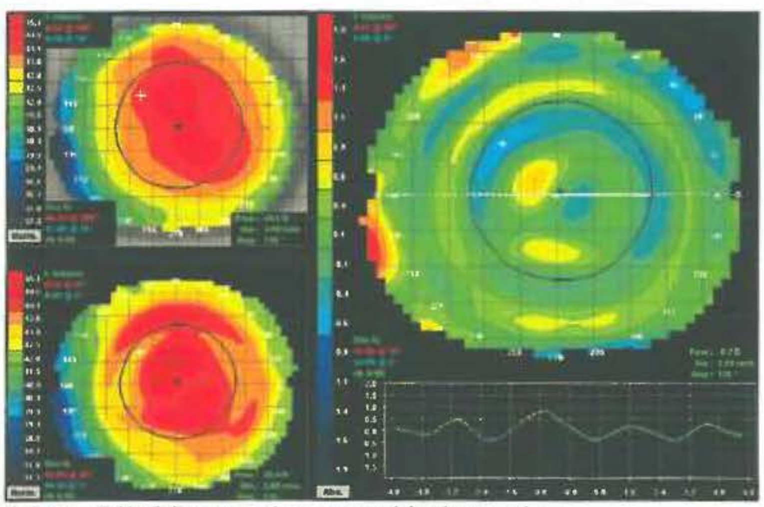


(Figure 31)



(Figure 32) OS slit lamp examination

- well centered treatment zone with mid peripheral relief zone
- 0.25mm movement in primary gaze and 0.5mm movement in up gaze
- good limbal coverage
- no flutting
- no bubbles



(Figure 33) OS corneal topographical mapping

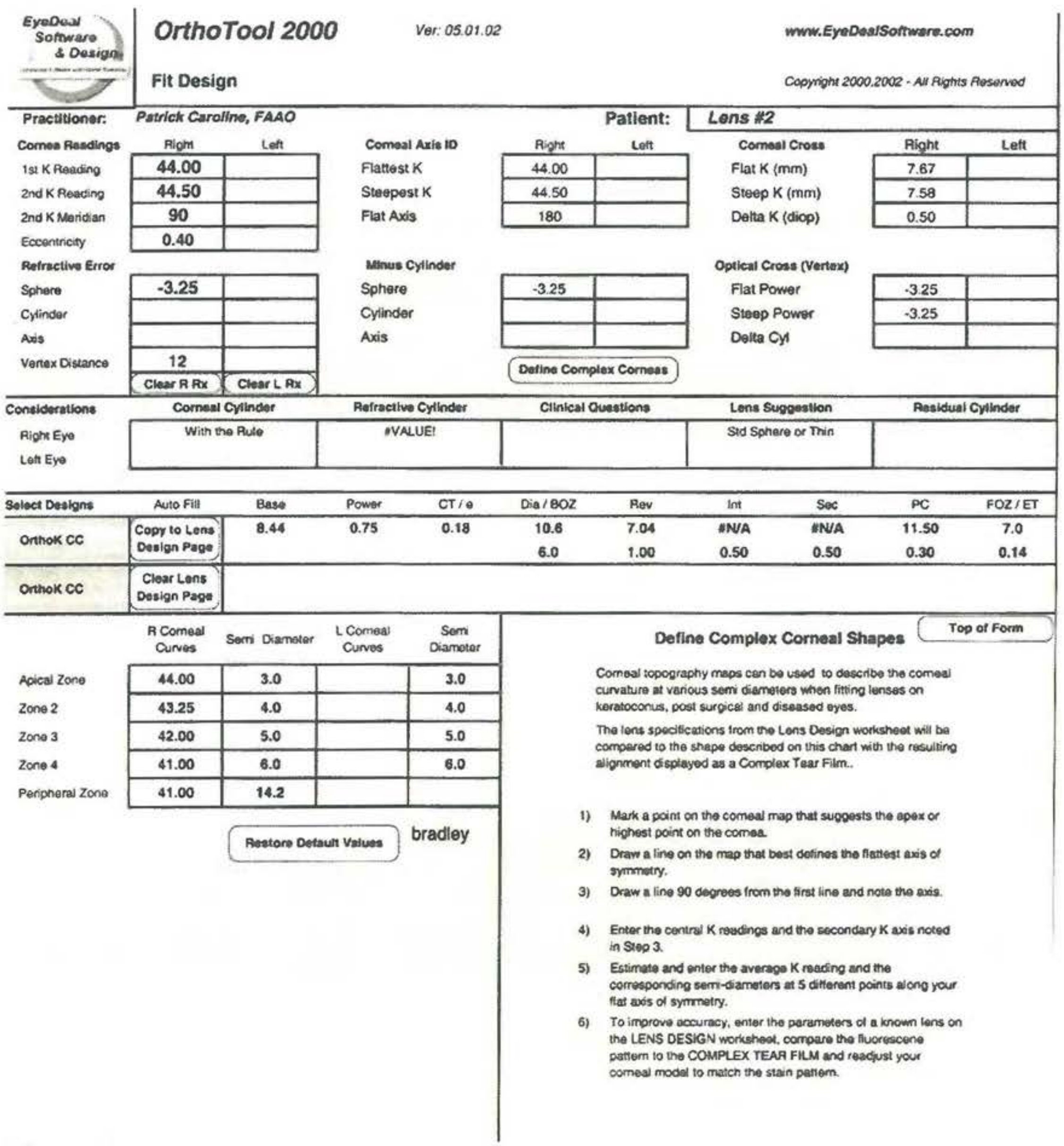
- small topographical changes were created
- areas of central flattening and steepening with circumferential ring of steepening
- maximal central flattening: -0.75 D

Conclusion: This contact lens created a central island.

5.8 -- Lens 5

OS:	Power:	plano
	Base curve:	8.5
	Eccentricity:	1.5
	Central thickness:	0.3
	Diameter:	14.2
	Reverse curve radius:	7.24
	Over refraction:	-4.25/ -0.5/ 67°

Aspheric Reverse Geometry Lens Design



EyeDeal Software & Design

OrthoTool 2000 Ver: 05.01.02 www.EyeDealSoftware.com

Fit Design Copyright 2000.2002 - All Rights Reserved

Practitioner: Patrick Caroline, FAAO Patient: Lens #2

Cornea Readings	Right	Left	Corneal Axis ID	Right	Left	Corneal Cross	Right	Left
1st K Reading	44.00		Flattest K	44.00		Flat K (mm)	7.67	
2nd K Reading	44.50		Steepest K	44.50		Steep K (mm)	7.58	
2nd K Meridian	90		Flat Axis	180		Delta K (diop)	0.50	
Eccentricity	0.40							
Refractive Error			Minus Cylinder			Optical Cross (Vertex)		
Sphere	-3.25		Sphere	-3.25		Flat Power	-3.25	
Cylinder			Cylinder			Steep Power	-3.25	
Axis			Axis			Delta Cyl		
Vertex Distance	12							

Clear R Rx Clear L Rx Define Complex Corneas

Considerations	Corneal Cylinder	Refractive Cylinder	Clinical Questions	Lens Suggestion	Residual Cylinder
Right Eye	With the Rule	#VALUE!		Std Sphere or Thin	
Left Eye					

Select Designs	Auto Fill	Base	Power	CT / e	Dia / BOZ	Rev	Int	Sec	PC	FOZ / ET
OrthoK CC	Copy to Lens Design Page	8.44	0.75	0.18	10.6	7.04	#N/A	#N/A	11.50	7.0
					6.0	1.00	0.50	0.50	0.30	0.14
OrthoK CC	Clear Lens Design Page									

	R Corneal Curves	Semi Diameter	L Corneal Curves	Semi Diameter
Apical Zone	44.00	3.0		3.0
Zone 2	43.25	4.0		4.0
Zone 3	42.00	5.0		5.0
Zone 4	41.00	6.0		6.0
Peripheral Zone	41.00	14.2		

Restore Default Values bradley

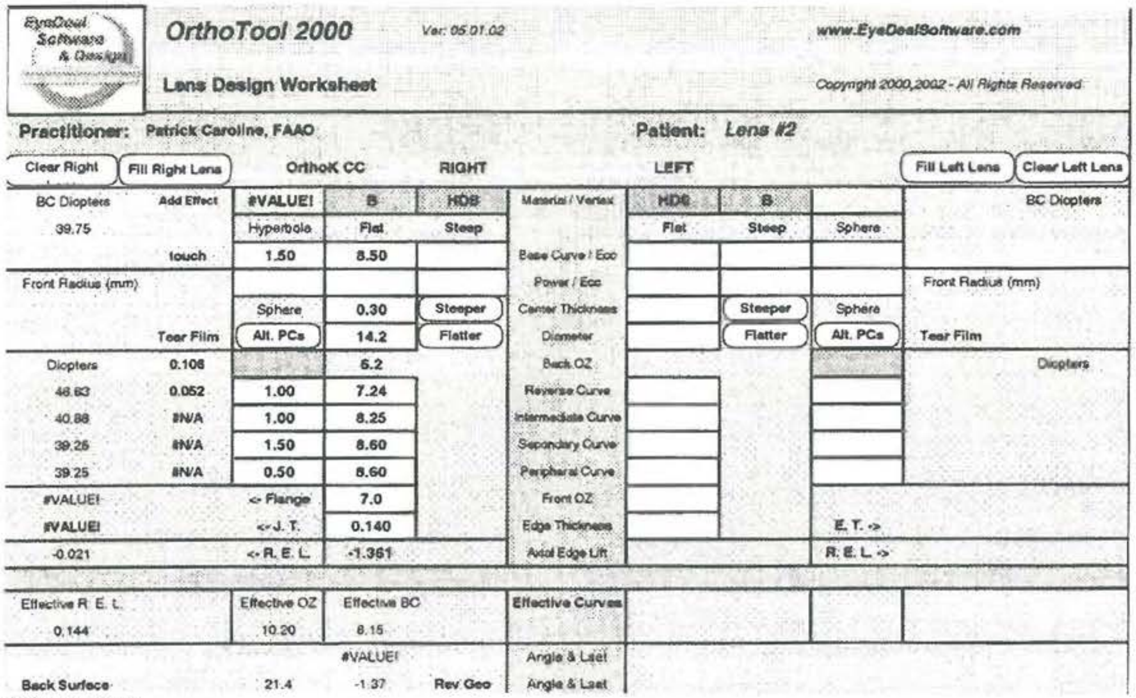
Define Complex Corneal Shapes Top of Form

Corneal topography maps can be used to describe the corneal curvature at various semi diameters when fitting lenses on keratoconus, post surgical and diseased eyes.

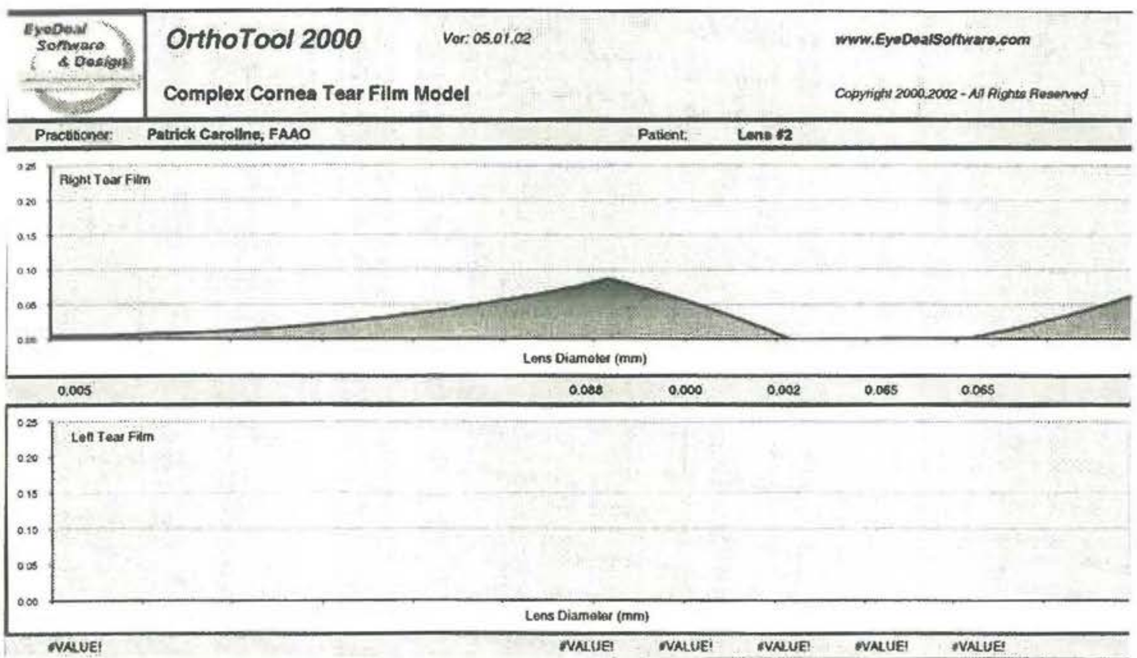
The lens specifications from the Lens Design worksheet will be compared to the shape described on this chart with the resulting alignment displayed as a Complex Tear Film..

1) Mark a point on the corneal map that suggests the apex or highest point on the cornea.
2) Draw a line on the map that best defines the flattest axis of symmetry.
3) Draw a line 90 degrees from the first line and note the axis.
4) Enter the central K readings and the secondary K axis noted in Step 3.
5) Estimate and enter the average K reading and the corresponding semi-diameters at 5 different points along your flat axis of symmetry.
6) To improve accuracy, enter the parameters of a known lens on the LENS DESIGN worksheet, compare the fluorescene pattern to the COMPLEX TEAR FILM and readjust your corneal model to match the stain pattern.

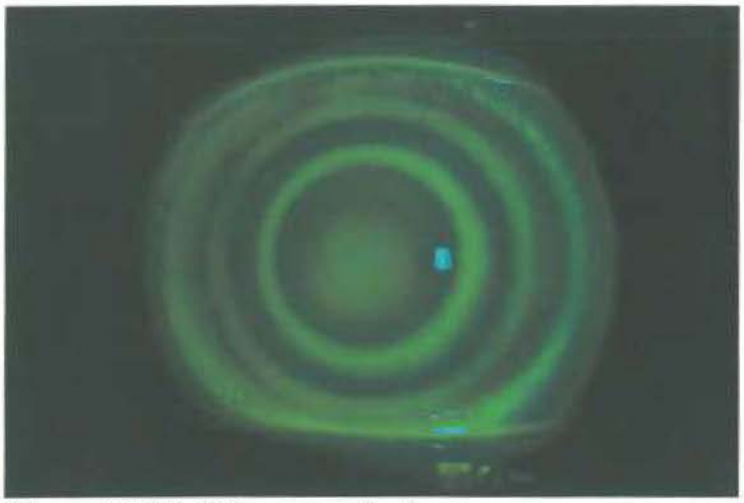
(Figure 34)



(Figure 35)

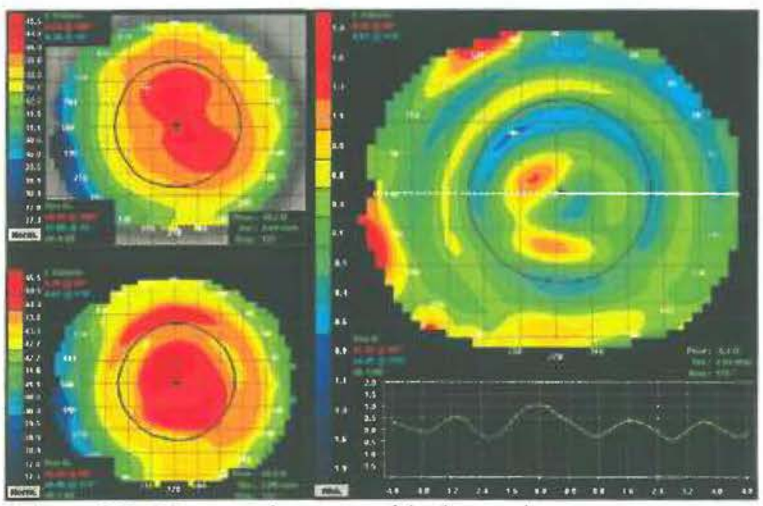


(Figure 36)



(Figure 37) OS slit lamp examination

- well centered treatment zone with mid peripheral relief zone
- 0.25mm movement in primary gaze and 0.5mm movement in up gaze
- good limbal coverage
- no flutting
- no bubbles



(Figure 38) OS corneal topographical mapping

- topographical changes were created
- areas of central flattening and steepening with circumferential ring of steepening
- maximal central flattening: -0.75 D
- central island was created

Conclusion: The increasing amount of asphericity did not resolve the central island.

Chapter 6

Pilot Study C

6.1 -- Comparing Two Different Kinds Of Reverse Geometry Silicone Hydrogel Contact Lens Materials For Daily Wear

Start date:	May, 22nd 2007
Completion date:	June, 12th 2007

Methods: Eight hours of daily wear reverse geometry soft contact lenses for the reduction of myopia.

Subject: male/ 25 years old/ Caucasian

Spectacle Rx OD:	-3.25 DS
Spectacle Rx OS:	-3.25 DS
Keratometry OD:	44.00/44.50 @ 11°/101°
Keratometry OS:	44.00/44.50 @ 19°/109°
Spectacle VA OD:	20/15
Spectacle VA OS:	20/15
Spectacle VA OU:	20/15

Contact Lens Parameters 1: Experimental Silicone Hydrogel Material

Contact Lens Parameters 2:

Material:	Benz hioxifilcon A
Water content:	59%
Oxygen permeability (DK):	21

1. Contact Lens Manufacturer: MedLens Innovations, Inc.
1325 Progress Drive
Front Royal, Virginia 22630

2. Contact Lens Manufacturer: Paragon Vision Science
947 E. Impala Avenue
Mesa, Arizona 85204

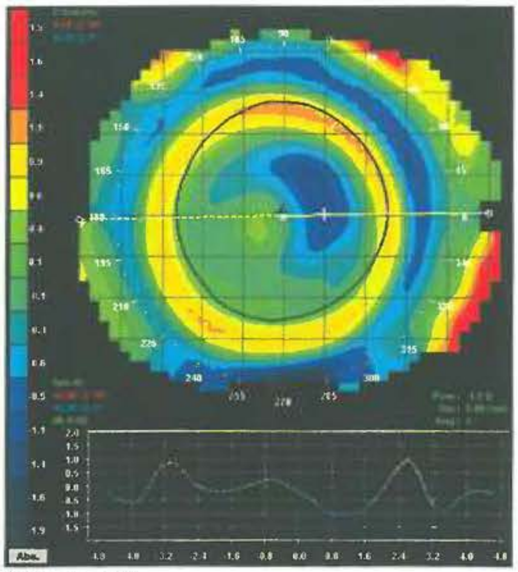
Conclusions: Soft contact lens materials, whether silicone hydrogel or traditional HEMA, appear to yield similar topographical results when reverse geometry soft contact lenses are manufactured in the same parameters and worn on a daily basis.

6.2 -- Summary

1 -- Spherical Reverse Geometry Lens Design

Lens 1a -- Manufacturer: MedLens

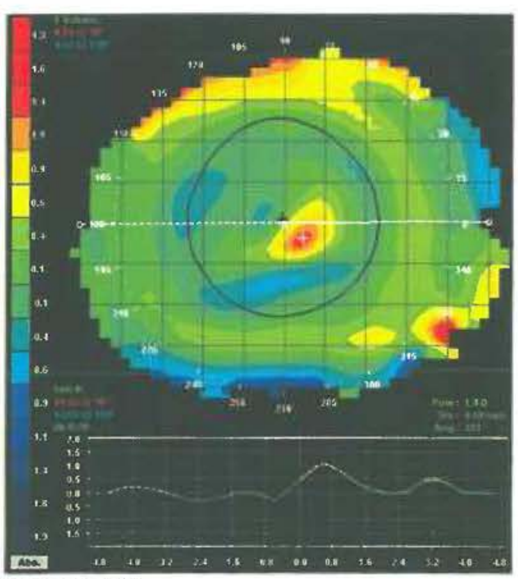
base curve: 8.5; diameter: 14.2; central thickness: 0.3



(Figure 39)

Lens 1b -- Manufacturer: Paragon

base curve: 8.5; diameter: 14.2; central thickness: 0.1

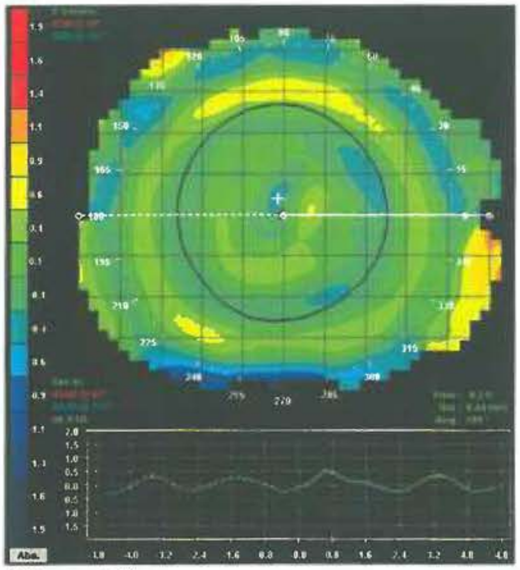


(Figure 40)

2 -- Aspheric Reverse Geometry Lens Design

Lens 2a -- Manufacturer: MedLens

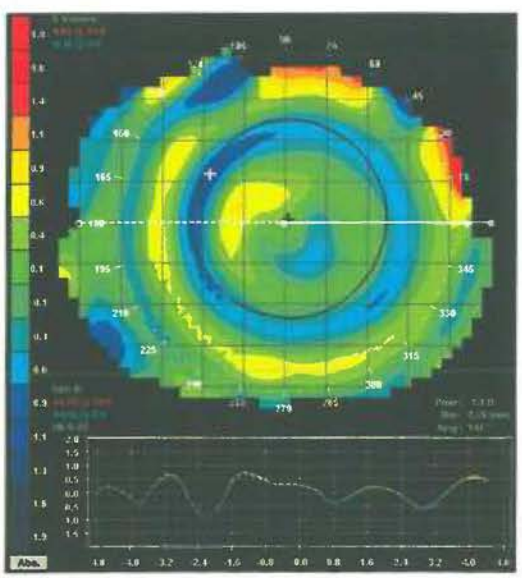
base curve: 8.5; diameter: 14.2; central thickness: 0.3



(Figure 41)

Lens 2b -- Manufacturer: Paragon

base curve: 8.5; diameter: 14.19; central thickness: 0.12

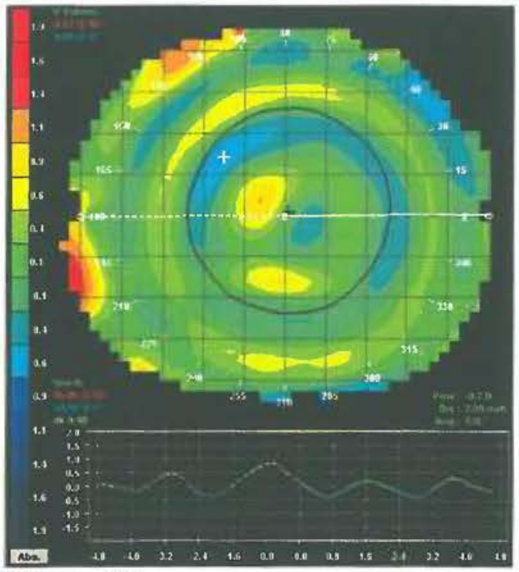


(Figure 42)

3 -- Aspheric Reverse Geometry Lens Design

Lens 3a -- Manufacturer: MedLens

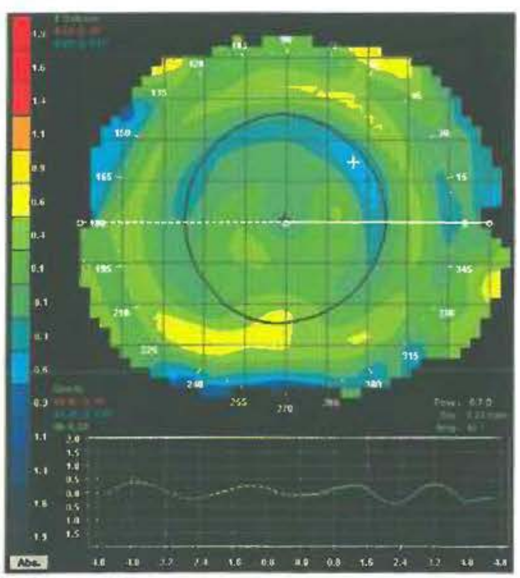
base curve: 8.5; diameter: 14.2; central thickness: 0.3



(Figure 43)

Lens 3b -- Manufacturer: Paragon

base curve: 8.5; diameter: 14.19; central thickness: 0.12

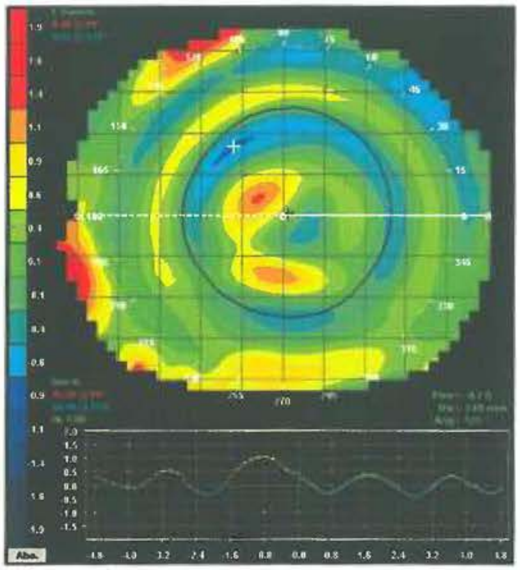


(Figure 44)

4 -- Aspheric Reverse Geometry Lens Design

Lens 4a -- Manufacturer: MedLens

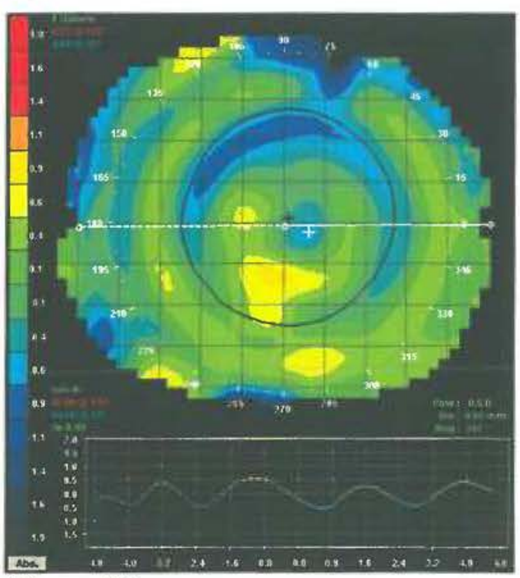
base curve: 8.5; diameter: 14.2; central thickness: 0.3



(Figure 45)

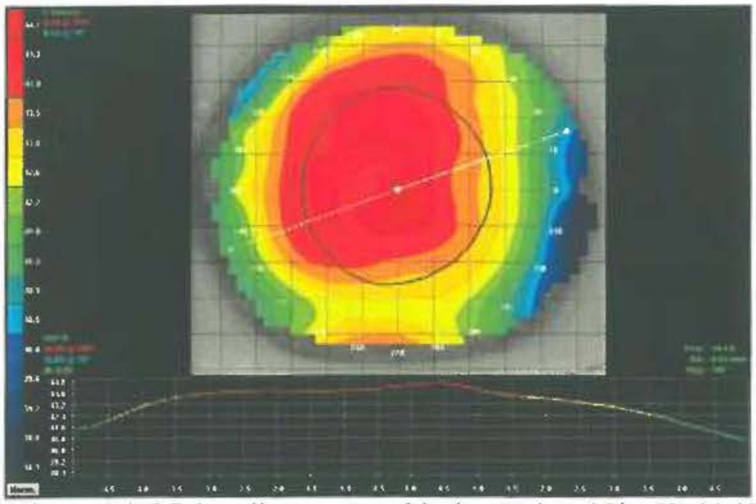
Lens 4b -- Manufacturer: Paragon

base curve: 8.5; diameter: 14.2; central thickness: 0.15



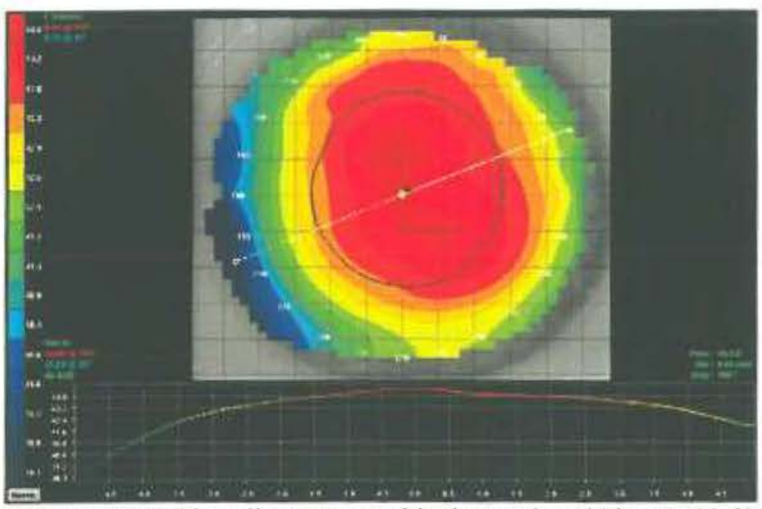
(Figure 46)

6.3 -- Baseline Topographical Mappings



(Figure 47) OD baseline topographical mappings/ Sim K: 44.40/43.80 @ 109°/19°

- mild/regular with the rule astigmatism



(Figure 48) OS baseline topographical mappings/ Sim K: 44.60/43.80 @ 112°/22°

- mild/regular with the rule astigmatism

6.4 -- 1. Lens Design

Spherical Reverse Geometry Lens Design

EyeDeal Software & Design

OrthoTool 2000 Ver: 05.01.02 www.EyeDealSoftware.com

Fit Design

Practitioner: Patrick Caroline, FAAO — Patient: Lens #1

Cornea Readings	Right	Left	Corneal Axis ID	Right	Left	Corneal Cross	Right	Left
1st K Reading	44.00		Flattest K	44.00		Flat K (mm)	7.67	
2nd K Reading	44.50		Steepest K	44.50		Steep K (mm)	7.58	
2nd K Meridian	90		Flat Axis	180		Delta K (diop)	0.50	
Eccentricity	0.40							
Refractive Error			Minus Cylinder			Optical Cross (Vertex)		
Sphere	-3.25		Sphere	-3.25		Flat Power	-3.25	
Cylinder			Cylinder			Steep Power	-3.25	
Axis			Axis			Delta Cyl		
Vertex Distance	12							
	Clear R Rx	Clear L Rx		Define Complex Corneas				

Considerations	Corneal Cylinder	Refractive Cylinder	Clinical Questions	Lens Suggestion	Residual Cylinder
Right Eye	With the Rule	#VALUE!		Std Sphere or Thin	
Left Eye					

Select Designs	Auto Fill	Base	Power	CT / e	Dia / BOZ	Rev	Int	Sec	PC	FOZ / ET
OrthoK CC	Copy to Lens Design Page	8.44	0.75	0.18	10.6	7.04	#N/A	#N/A	11.50	7.0
					6.0	1.00	0.50	0.50	0.30	0.14
OrthoK CC	Clear Lens Design Page									

	R Corneal Curves	Semi Diameter	L Corneal Curves	Semi Diameter
Apical Zone	44.00	3.0		3.0
Zone 2	43.25	4.0		4.0
Zone 3	42.00	5.0		5.0
Zone 4	41.00	6.0		6.0
Peripheral Zone	41.00	14.2		

Restore Default Values bradley

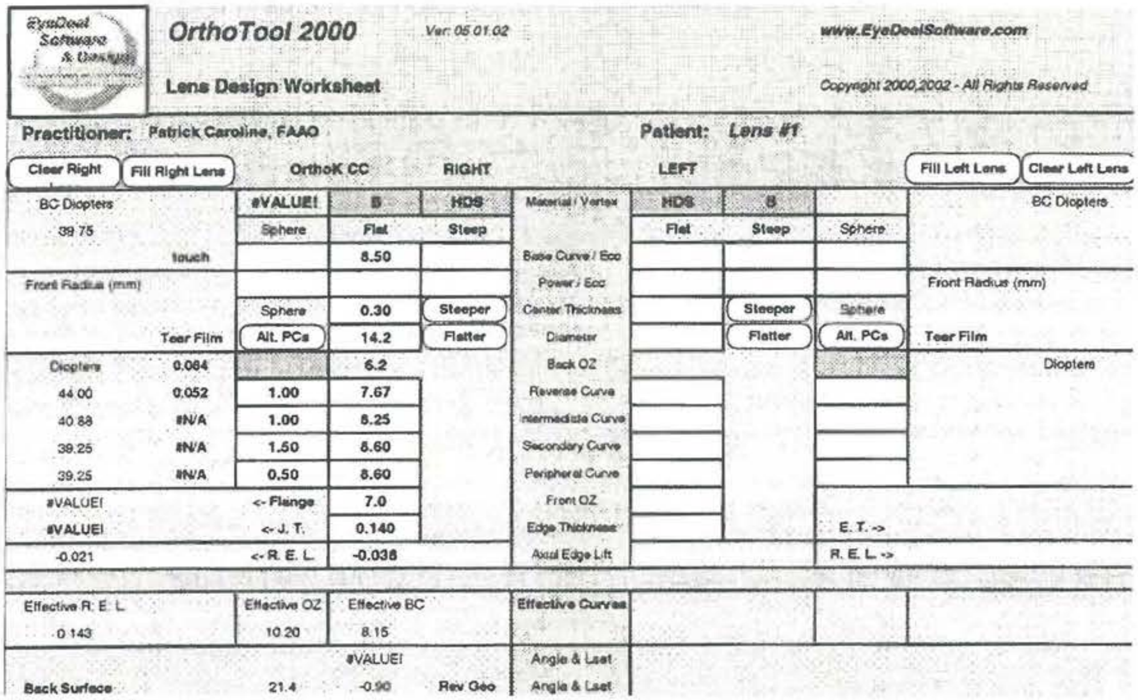
Define Complex Corneal Shapes Top of Form

Corneal topography maps can be used to describe the corneal curvature at various semi diameters when fitting lenses on keratoconus, post surgical and diseased eyes.

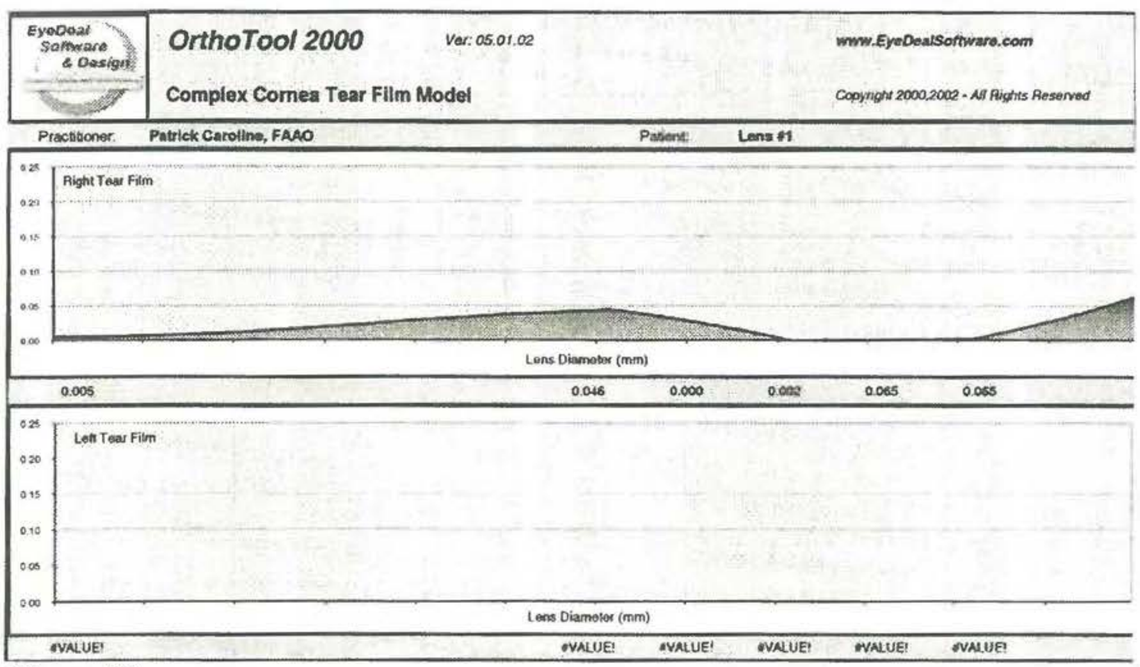
The lens specifications from the Lens Design worksheet will be compared to the shape described on this chart with the resulting alignment displayed as a Complex Tear Film..

1) Mark a point on the corneal map that suggests the apex or highest point on the cornea.
2) Draw a line on the map that best defines the flattest axis of symmetry.
3) Draw a line 90 degrees from the first line and note the axis.
4) Enter the central K readings and the secondary K axis noted in Step 3.
5) Estimate and enter the average K reading and the corresponding semi-diameters at 5 different points along your flat axis of symmetry.
6) To improve accuracy, enter the parameters of a known lens on the LENS DESIGN worksheet, compare the fluorescene pattern to the COMPLEX TEAR FILM and readjust your corneal model to match the stain pattern.

(Figure 49)



(Figure 50)

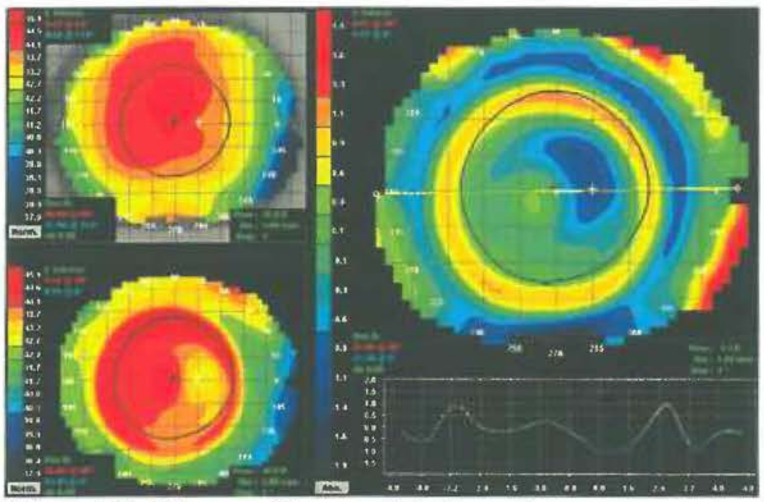


(Figure 51)

Lens 1a

Manufacturer: MedLens

OD:	Power:	plano
	Base curve:	8.5
	Central thickness:	0.3
	Diameter:	14.2
	Reverse curve radius:	7.67



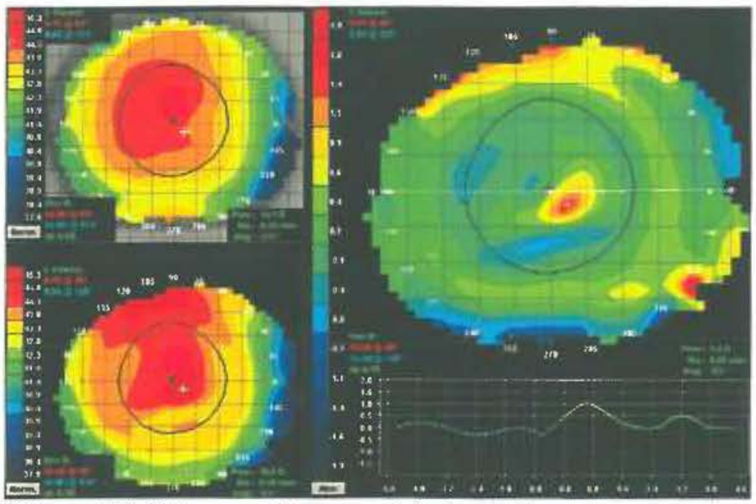
(Figure 52) OD corneal topographical mapping

- topographical changes were created
- well centered treatment zone with ring of mid-peripheral steepening and area temporal to center of steepening within treatment zone with adjacent area of nasal flattening
- maximum central flattening: -1.12 D

Lens 1b

Manufacturer: Paragon

OD:	Power:	plano
	Base curve:	8.5
	Central thickness:	0.1
	Diameter:	14.2
	Base curve Sag.:	3.721

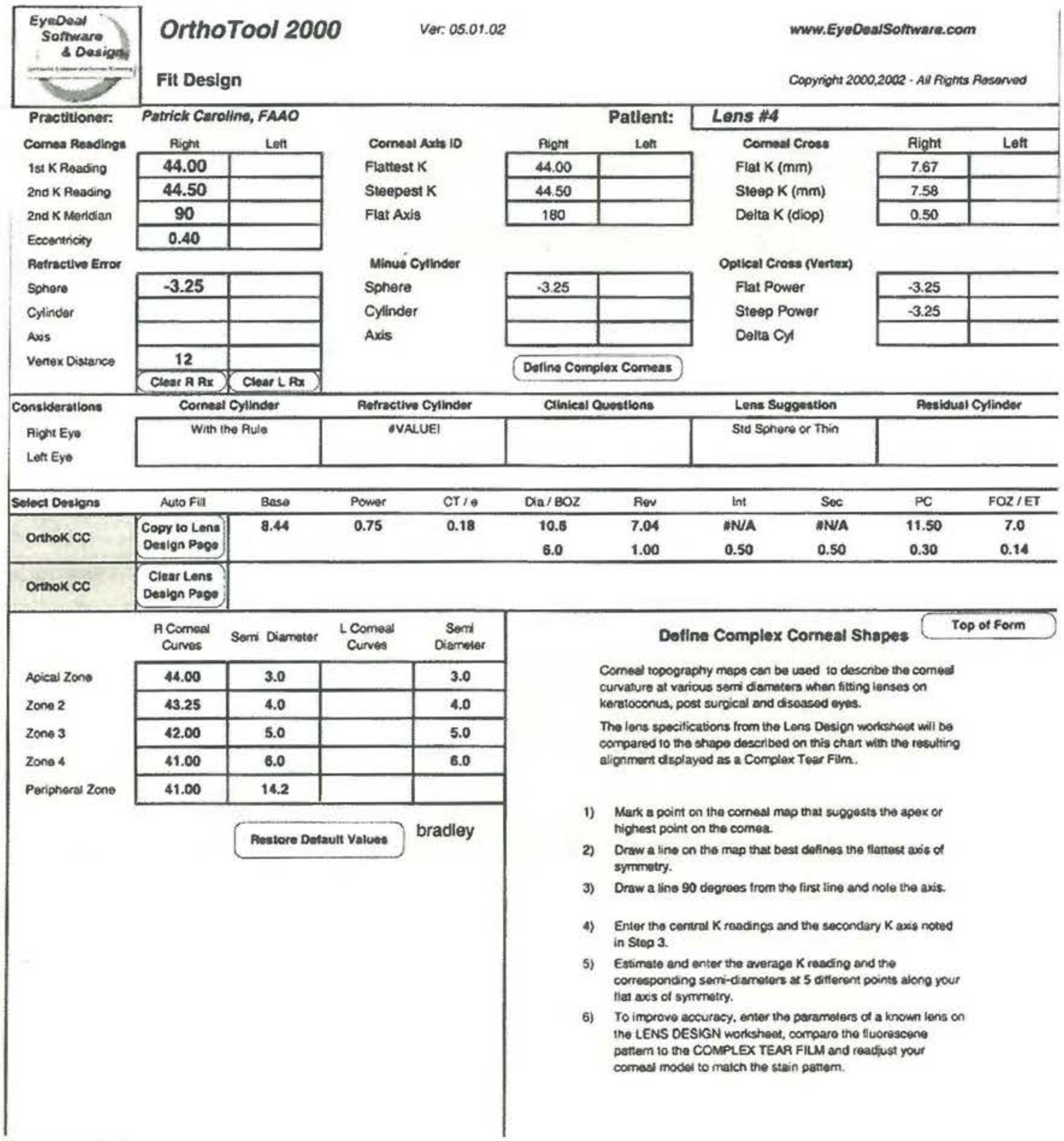


(Figure 53) OD corneal topographical mapping

- topographical changes were created
- areas of central flattening and steepening with circumferential ring of steepening
- no change in power
- maximum central flattening: -0.62 D

6.5 – 2. Lens Design

Aspheric Reverse Geometry Lens Design



EyeDeal Software & Design

OrthoTool 2000 Ver: 05.01.02 www.EyeDealSoftware.com

Fit Design Copyright 2000,2002 - All Rights Reserved

Practitioner: Patrick Caroline, FAAO Patient: Lens #4

Cornea Readings	Right	Left	Corneal Axis ID	Right	Left	Corneal Cross	Right	Left
1st K Reading	44.00		Flattest K	44.00		Flat K (mm)	7.67	
2nd K Reading	44.50		Steepest K	44.50		Steep K (mm)	7.58	
2nd K Meridian	90		Flat Axis	180		Delta K (diop)	0.50	
Eccentricity	0.40							
Refractive Error			Minus Cylinder			Optical Cross (Vertex)		
Sphere	-3.25		Sphere	-3.25		Flat Power	-3.25	
Cylinder			Cylinder			Steep Power	-3.25	
Axis			Axis			Delta Cyl		
Vertex Distance	12							

Clear R Rx Clear L Rx Define Complex Corneas

Considerations	Corneal Cylinder	Refractive Cylinder	Clinical Questions	Lens Suggestion	Residual Cylinder
Right Eye	With the Rule	#VALUE!		Std Sphere or Thin	
Left Eye					

Select Designs	Auto Fill	Base	Power	CT / e	Dia / BOZ	Rev	Int	Sec	PC	FOZ / ET
OrthoK CC	Copy to Lens Design Page	8.44	0.75	0.18	10.6	7.04	#N/A	#N/A	11.50	7.0
					6.0	1.00	0.50	0.50	0.30	0.14
OrthoK CC	Clear Lens Design Page									

	R Corneal Curves	Semi Diameter	L Corneal Curves	Semi Diameter
Apical Zone	44.00	3.0		3.0
Zone 2	43.25	4.0		4.0
Zone 3	42.00	5.0		5.0
Zone 4	41.00	6.0		6.0
Peripheral Zone	41.00	14.2		

Restore Default Values bradley

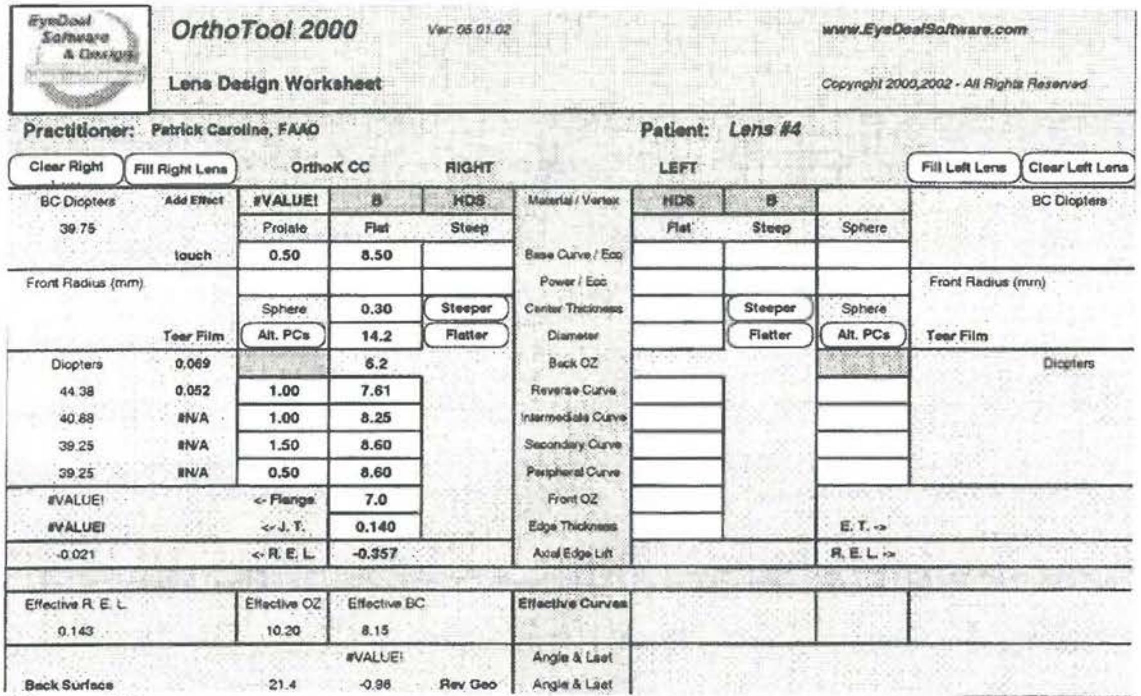
Define Complex Corneal Shapes Top of Form

Corneal topography maps can be used to describe the corneal curvature at various semi diameters when fitting lenses on keratoconus, post surgical and diseased eyes.

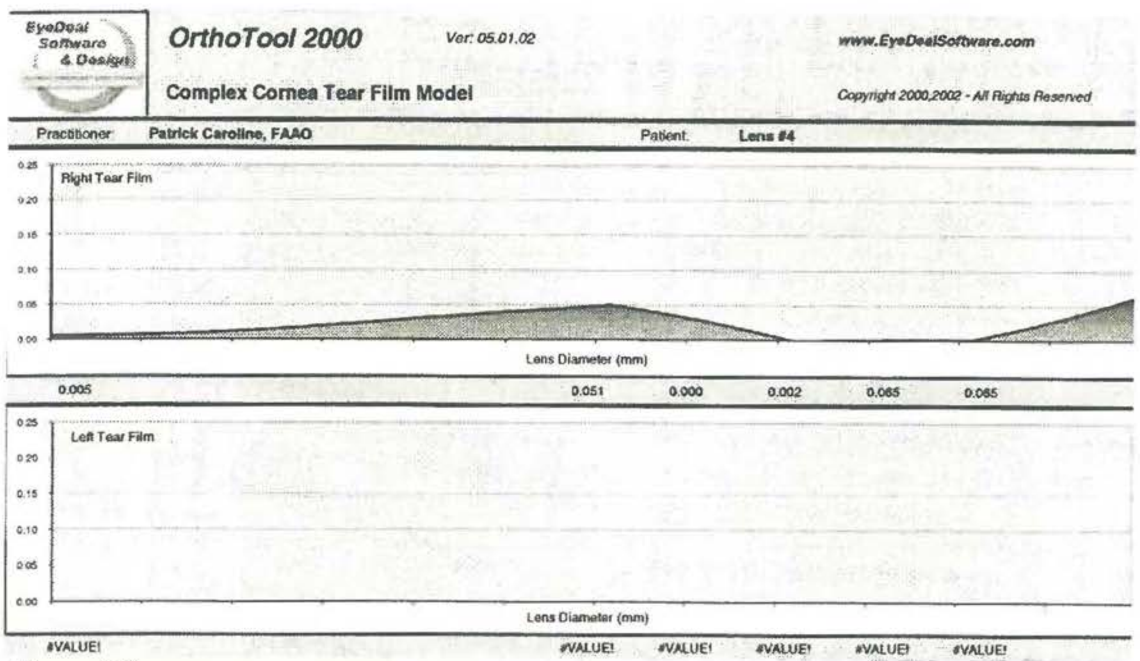
The lens specifications from the Lens Design worksheet will be compared to the shape described on this chart with the resulting alignment displayed as a Complex Tear Film.

1) Mark a point on the corneal map that suggests the apex or highest point on the cornea.
2) Draw a line on the map that best defines the flattest axis of symmetry.
3) Draw a line 90 degrees from the first line and note the axis.
4) Enter the central K readings and the secondary K axis noted in Step 3.
5) Estimate and enter the average K reading and the corresponding semi-diameters at 5 different points along your flat axis of symmetry.
6) To improve accuracy, enter the parameters of a known lens on the LENS DESIGN worksheet, compare the fluorescene pattern to the COMPLEX TEAR FILM and readjust your corneal model to match the stain pattern.

(Figure 54)



(Figure 55)

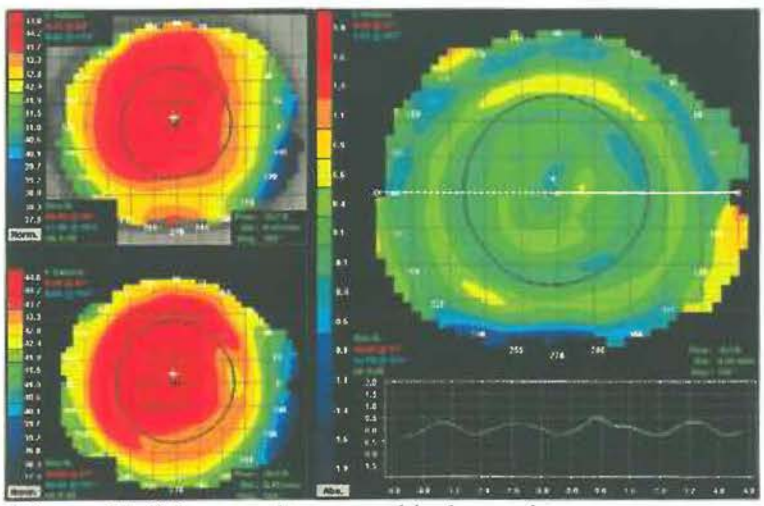


(Figure 56)

Lens 2a

Manufacturer: MedLens

OD:	Power:	plano
	Base curve:	8.5
	Eccentricity:	0.5
	Central thickness:	0.3
	Diameter:	14.2
	Reverse curve radius:	7.61



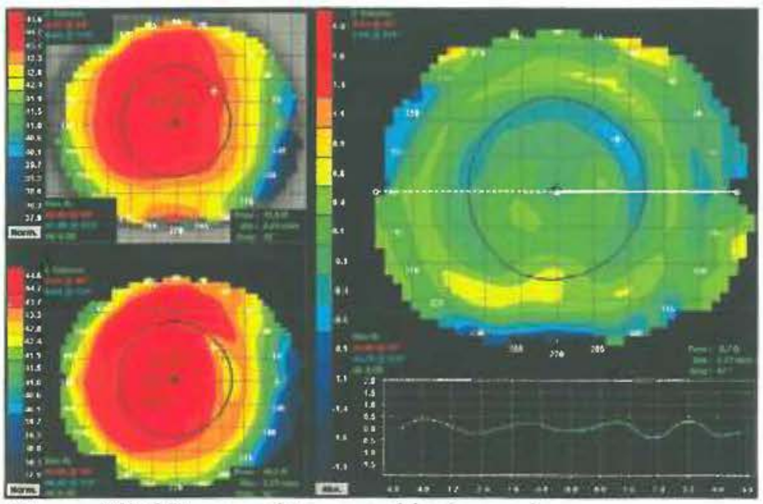
(Figure 57) OD corneal topographical mapping

- insignificant topographical changes were created
- areas of central flattening and steepening with circumferential ring of steepening
- no over refraction
- maximum central flattening: -0.37 D

Lens 2b

Manufacturer: Paragon

OD:	Power:	plano
	Base curve:	8.5
	Eccentricity:	0.5
	Central thickness:	0.12
	Diameter:	14.19
	Base curve Sag.:	3.723

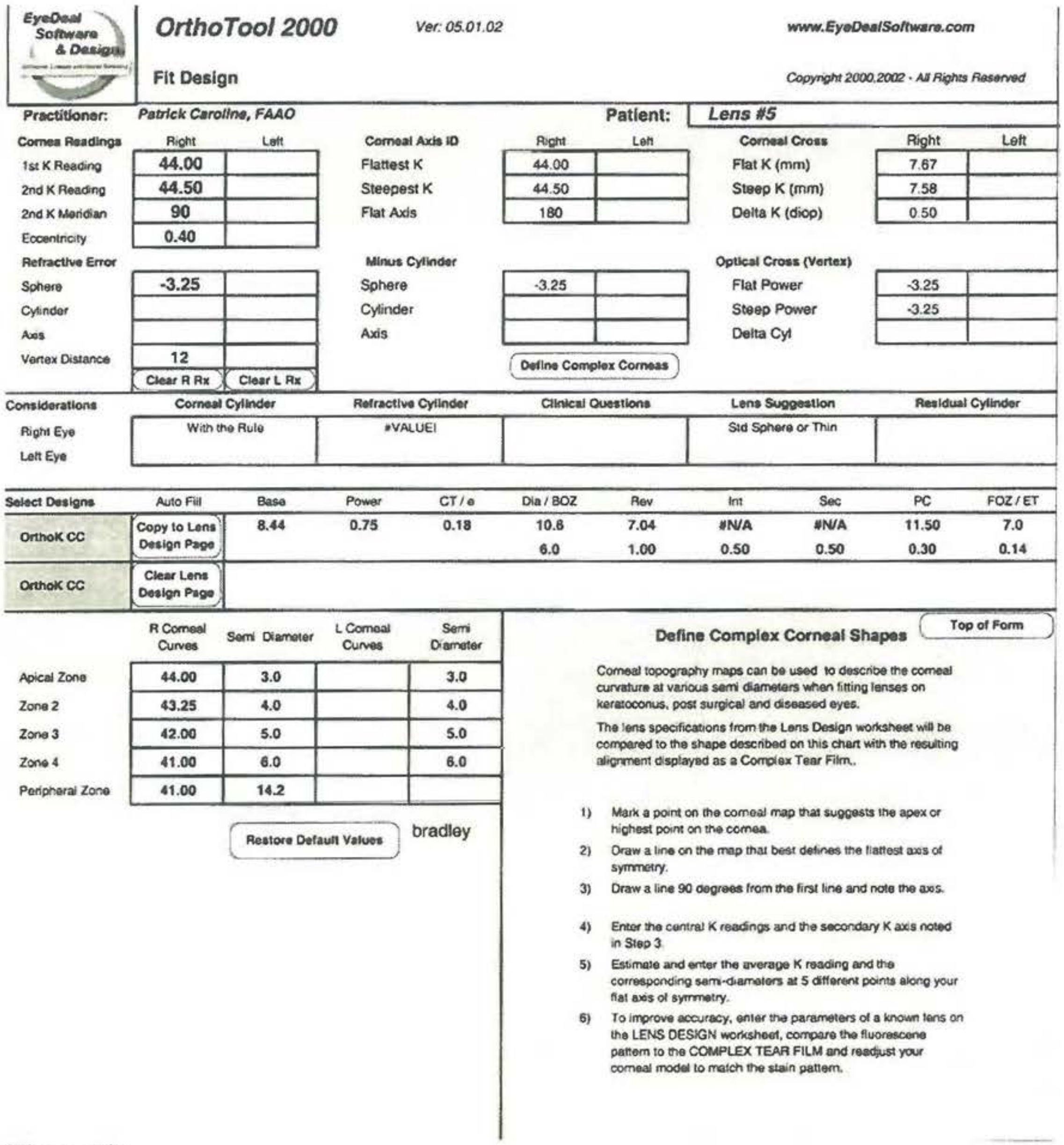


(Figure 58) OD corneal topographical mapping

- ring of flattening superior
- areas of central flattening and steepening with circumferential ring of steepening
- maximum central flattening: -0.75 D

6.6 -- 3. Lens Design

Aspheric Reverse Geometry Lens Design



EyeDeal Software & Design

OrthoTool 2000 Ver: 05.01.02 www.EyeDealSoftware.com

Fit Design

Practitioner: Patrick Caroline, FAAO Patient: Lens #5

Cornea Readings	Right	Left	Corneal Axis ID	Right	Left	Corneal Cross	Right	Left
1st K Reading	44.00		Flattest K	44.00		Flat K (mm)	7.67	
2nd K Reading	44.50		Steepest K	44.50		Steep K (mm)	7.58	
2nd K Meridian	90		Flat Axis	180		Delta K (diop)	0.50	
Eccentricity	0.40							
Refractive Error			Minus Cylinder			Optical Cross (Vertex)		
Sphere	-3.25		Sphere	-3.25		Flat Power	-3.25	
Cylinder			Cylinder			Steep Power	-3.25	
Axis			Axis			Delta Cyl		
Vertex Distance	12							

Clear R Rx | Clear L Rx | Define Complex Corneas

Considerations	Corneal Cylinder	Refractive Cylinder	Clinical Questions	Lens Suggestion	Residual Cylinder
Right Eye	With the Rule	#VALUE!		Std Sphere or Thin	
Left Eye					

Select Designs	Auto Fill	Base	Power	CT / e	Dia / BOZ	Rev	Int	Sec	PC	FOZ / ET
OrthoK CC	Copy to Lens Design Page	8.44	0.75	0.18	10.8	7.04	#N/A	#N/A	11.50	7.0
					6.0	1.00	0.50	0.50	0.30	0.14
OrthoK CC	Clear Lens Design Page									

	R Corneal Curves	Semi Diameter	L Corneal Curves	Semi Diameter
Apical Zone	44.00	3.0		3.0
Zone 2	43.25	4.0		4.0
Zone 3	42.00	5.0		5.0
Zone 4	41.00	6.0		6.0
Peripheral Zone	41.00	14.2		

Restore Default Values bradley

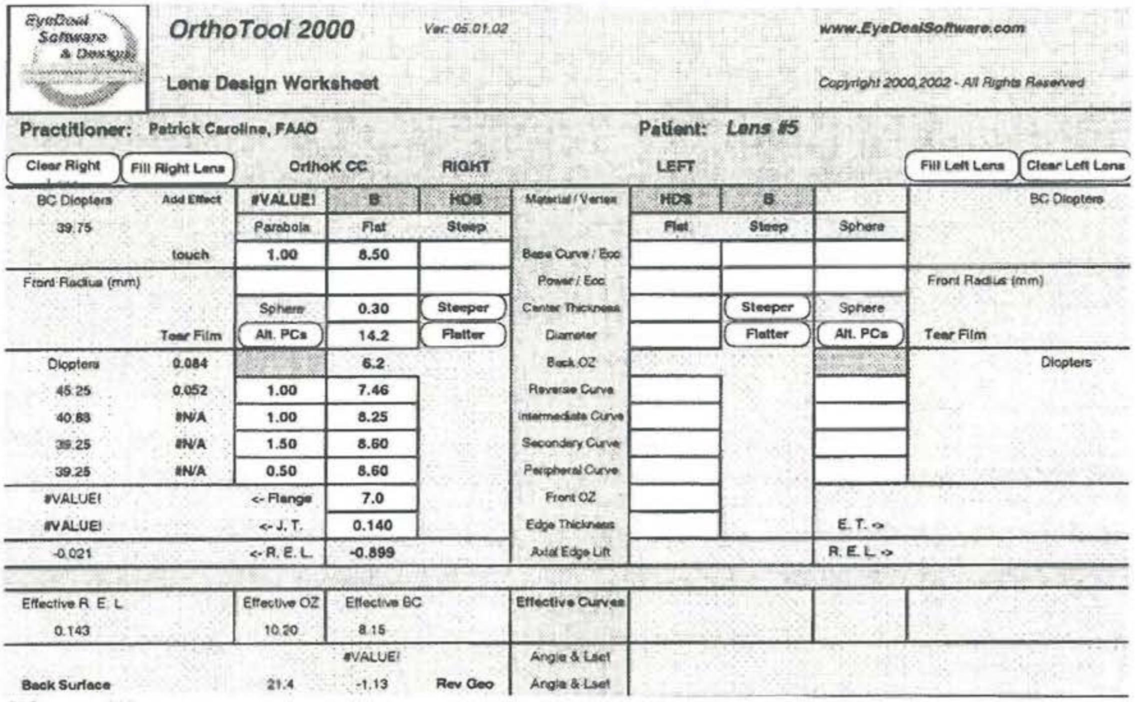
Define Complex Corneal Shapes Top of Form

Corneal topography maps can be used to describe the corneal curvature at various semi diameters when fitting lenses on keratoconus, post surgical and diseased eyes.

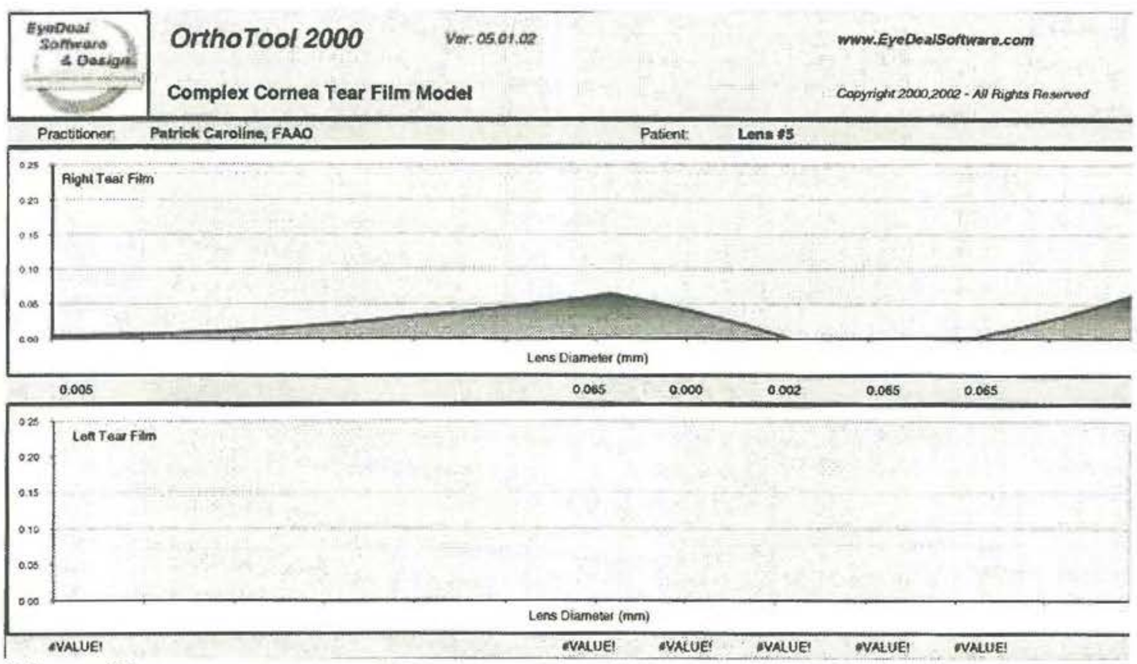
The lens specifications from the Lens Design worksheet will be compared to the shape described on this chart with the resulting alignment displayed as a Complex Tear Film.

1) Mark a point on the corneal map that suggests the apex or highest point on the cornea.
2) Draw a line on the map that best defines the flattest axis of symmetry.
3) Draw a line 90 degrees from the first line and note the axis.
4) Enter the central K readings and the secondary K axis noted in Step 3.
5) Estimate and enter the average K reading and the corresponding semi-diameters at 5 different points along your flat axis of symmetry.
6) To improve accuracy, enter the parameters of a known lens on the LENS DESIGN worksheet, compare the fluorescene pattern to the COMPLEX TEAR FILM and readjust your corneal model to match the stain pattern.

(Figure 59)



(Figure 60)

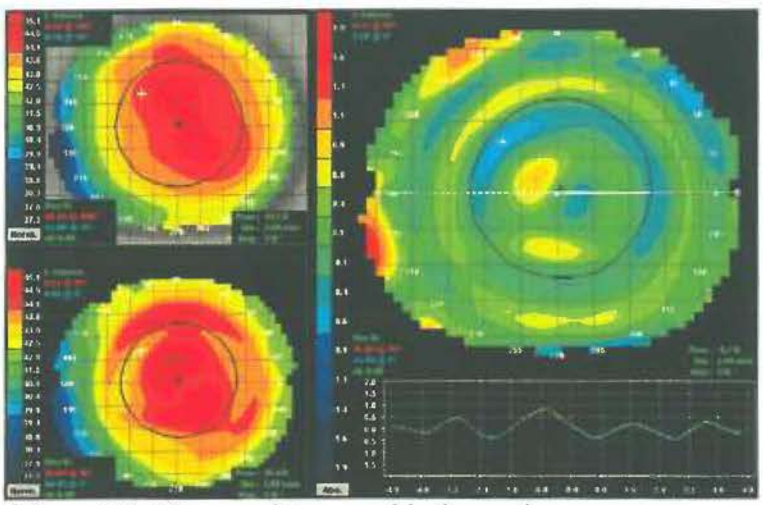


(Figure 61)

Lens 3a

Manufacturer: MedLens

OS:	Power:	plano
	Base curve:	8.5
	Eccentricity:	1.0
	Central thickness:	0.3
	Diameter:	14.2
	Reverse curve radius:	7.46



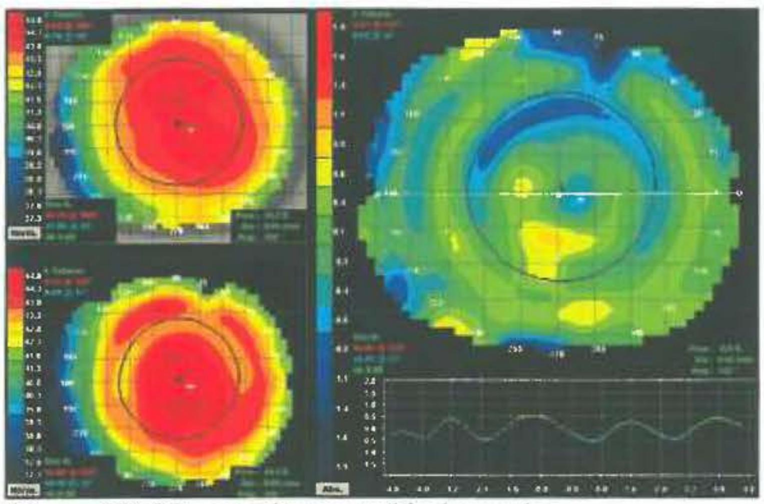
(Figure 62) OS corneal topographical mapping

- small topographical changes were created
- areas of central flattening and steepening with circumferential ring of steepening
- maximum central flattening: -0.75 D

Lens 3b

Manufacturer: Paragon

OS:	Power:	plano
	Base curve:	8.5
	Eccentricity:	1.0
	Central thickness:	0.12
	Diameter:	14.19
	Base curve sag.	3.722

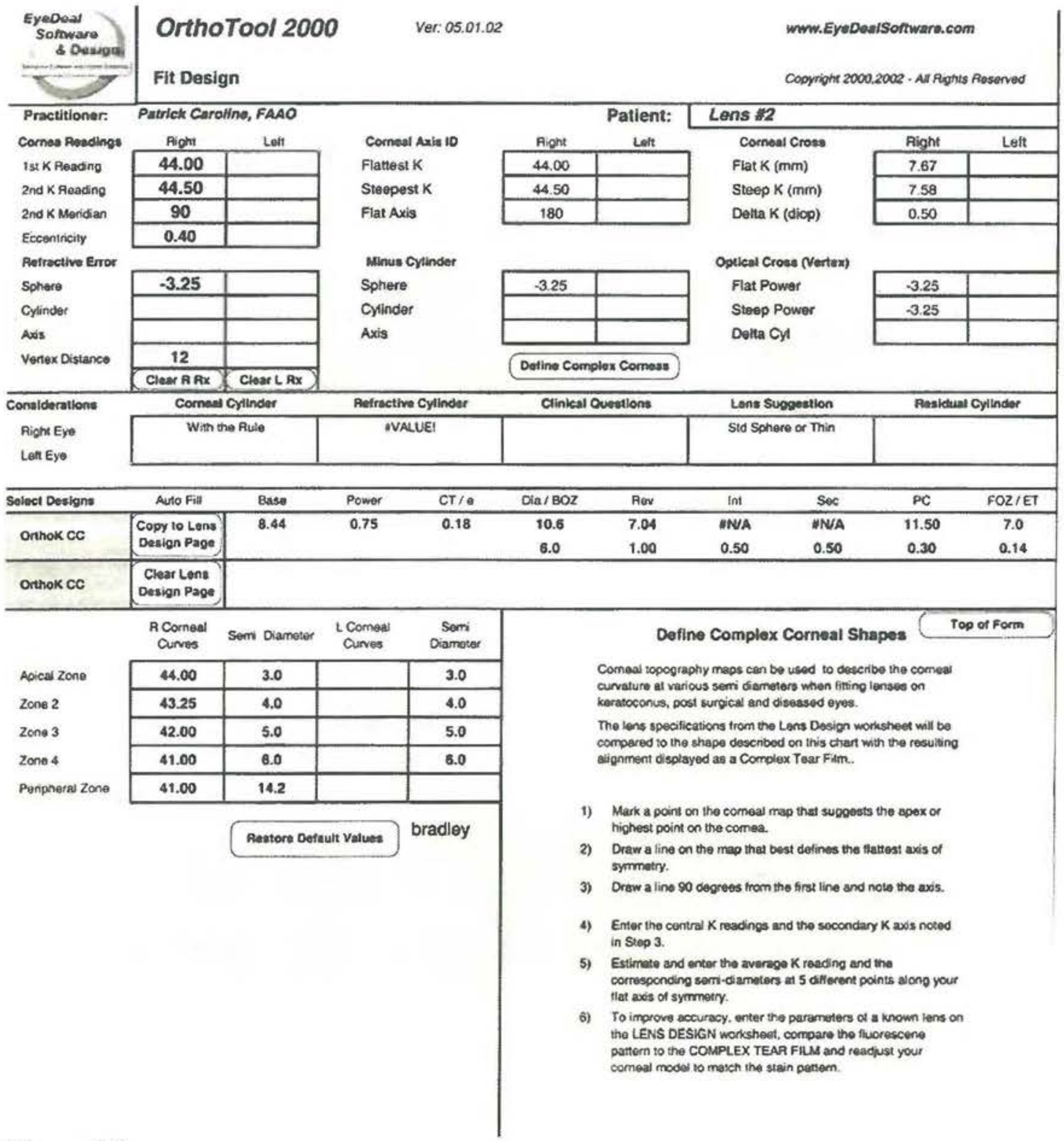


(Figure 63) OS corneal topographical mapping

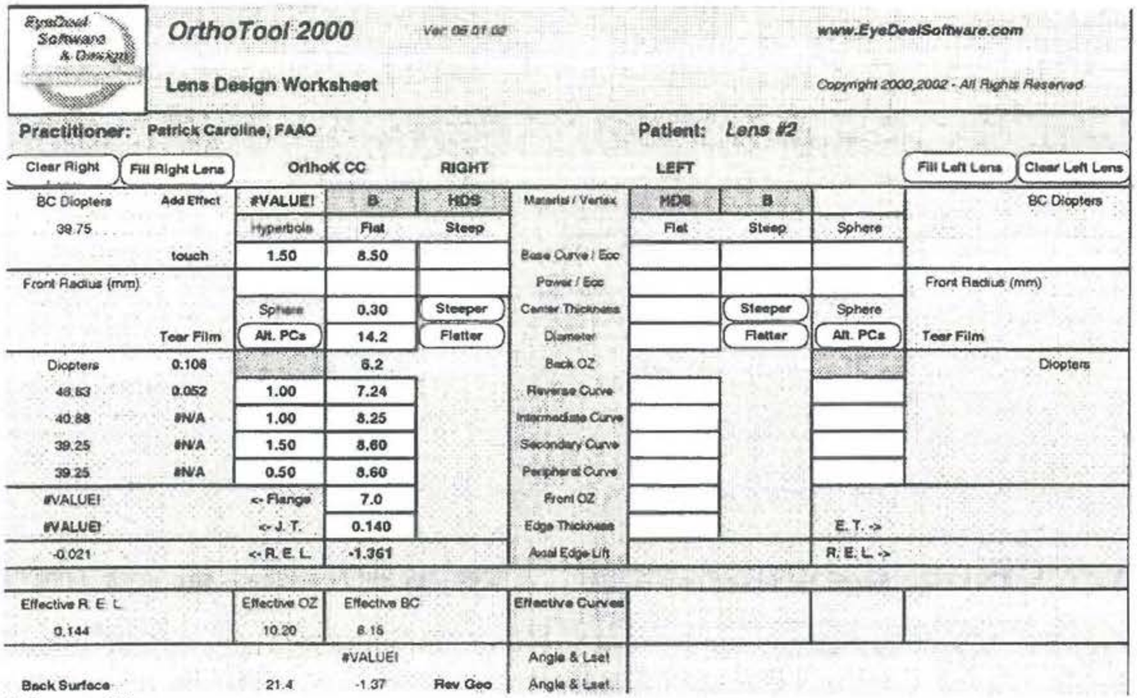
- superior/central flattening
- areas of central flattening and steepening with circumferential ring of steepening
- maximum central flattening: -0.87 D

6.7 -- 4. Lens Design

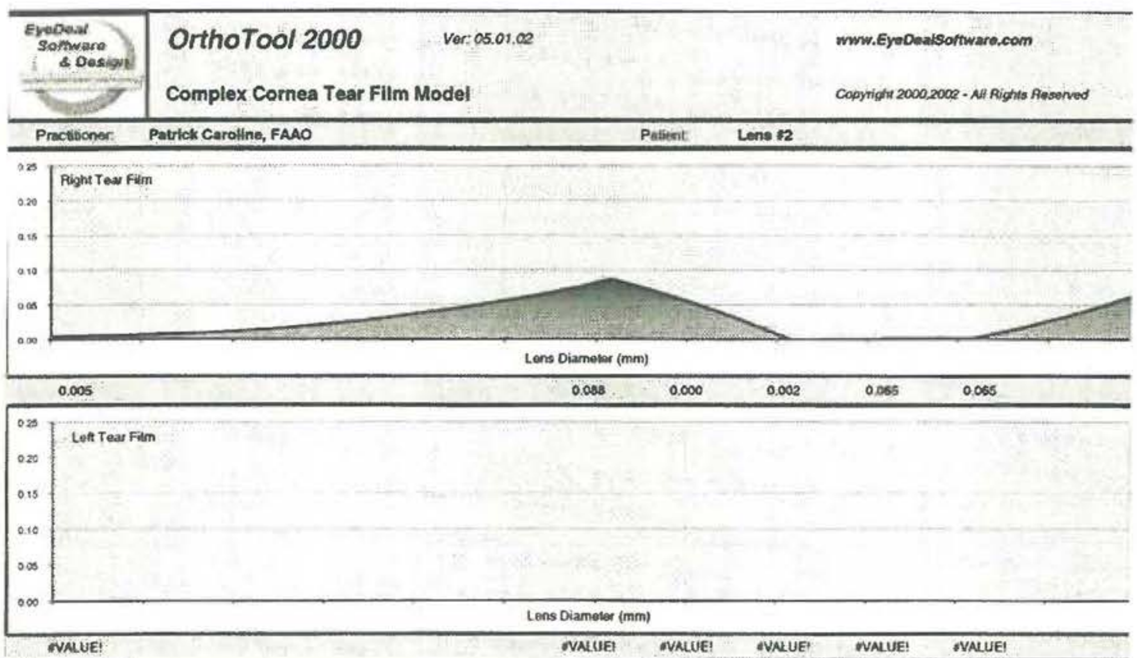
Aspheric Reverse Geometry Lens Design



(Figure 64)



(Figure 65)

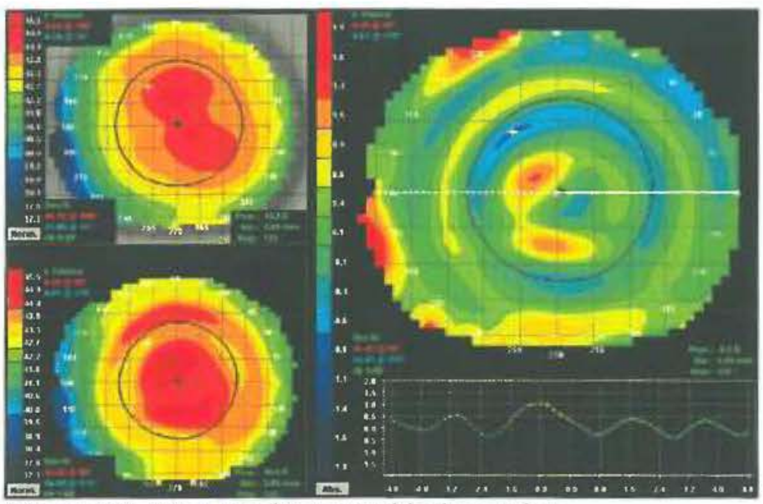


(Figure 66)

Lens 4a

Manufacturer: MedLens

OS:	Power:	plano
	Base curve:	8.5
	Eccentricity:	1.5
	Central thickness:	0.3
	Diameter:	14.2
	Reverse curve radius:	7.24



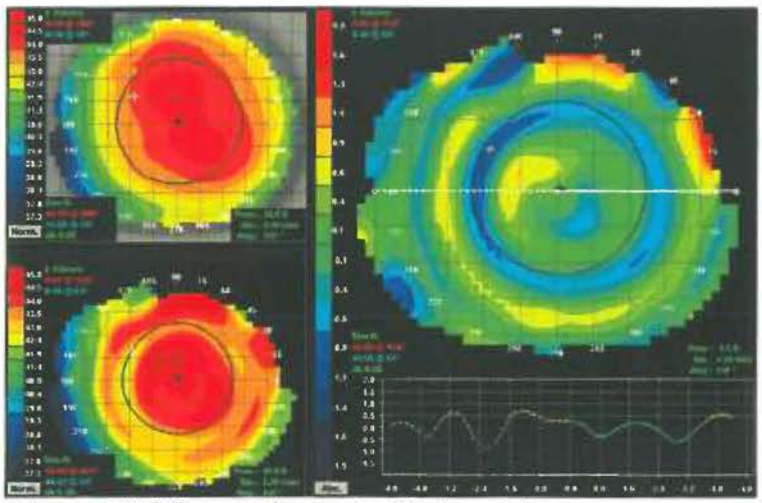
(Figure 67) OS corneal topographical mapping

- topographical changes were created
- areas of central flattening and steepening with circumferential ring of steepening
- maximum central flattening: -0.75 D
- central island was created

Lens 4b

Manufacturer: Paragon

OS:	Power:	plano
	Base curve:	8.5
	Eccentricity:	1.5
	Central thickness:	0.15
	Diameter:	14.19
	Base curve Sag.:	3.724



(Figure 68) OS corneal topographical mapping

- minimal topographical changes in the center
- no changes in power
- areas of central flattening and steepening with circumferential ring of steepening
- maximum central flattening: 1.12 D

Chapter 7

Pilot Study D

7.1 -- Reverse Geometry Silicone Hydrogel Contact Lenses For Daily Wear

Start date:	October, 15th 2007 (7 AM)
Completion date:	October, 15th 2007 (5 PM)

Methods: Ten hours of daily wear reverse geometry soft contact lenses for the reduction of myopia.

Subject: male/ 26 years old/ caucasian

Spectacle Rx OD:	-3.25 DS
Keratometry OD:	44.00/44.50 @ 11°/101°
Spectacle VA OD:	20/15
Unaided VA OD:	20/400

Contact Lens Parameters:

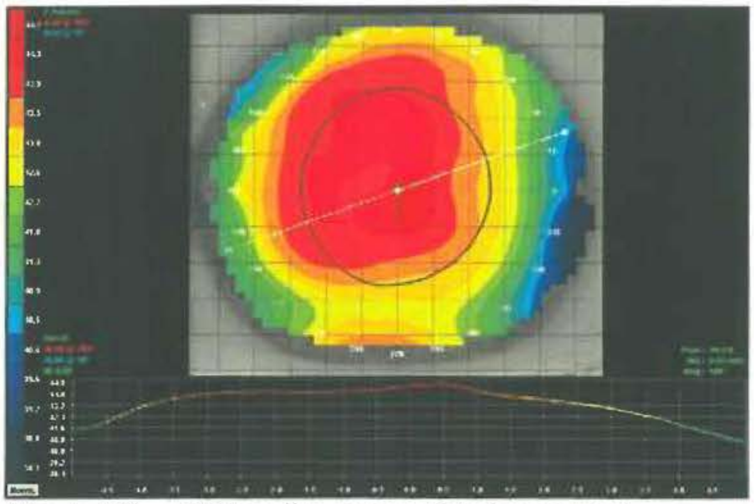
Base curve:	11.00 mm
Diameter:	14.2 mm
Power:	-3.25 D
Optic zone diameter:	6.22 mm
Eccentricity:	1.5
Material:	Benz hioxifilcon A
Water content:	59%
Oxygen permeability (DK):	21

Contact Lens Manufacturer:

MedLens Innovations, Inc.
1325 Progress Drive
Front Royal, Virginia 22630

Conclusions: Increased flattening of the central base curve beyond the 8.50, as would be calculated to reduce the amount of the subject myopia in a rigid lens, to 11.00 does not appear to create an effective treatment zone.

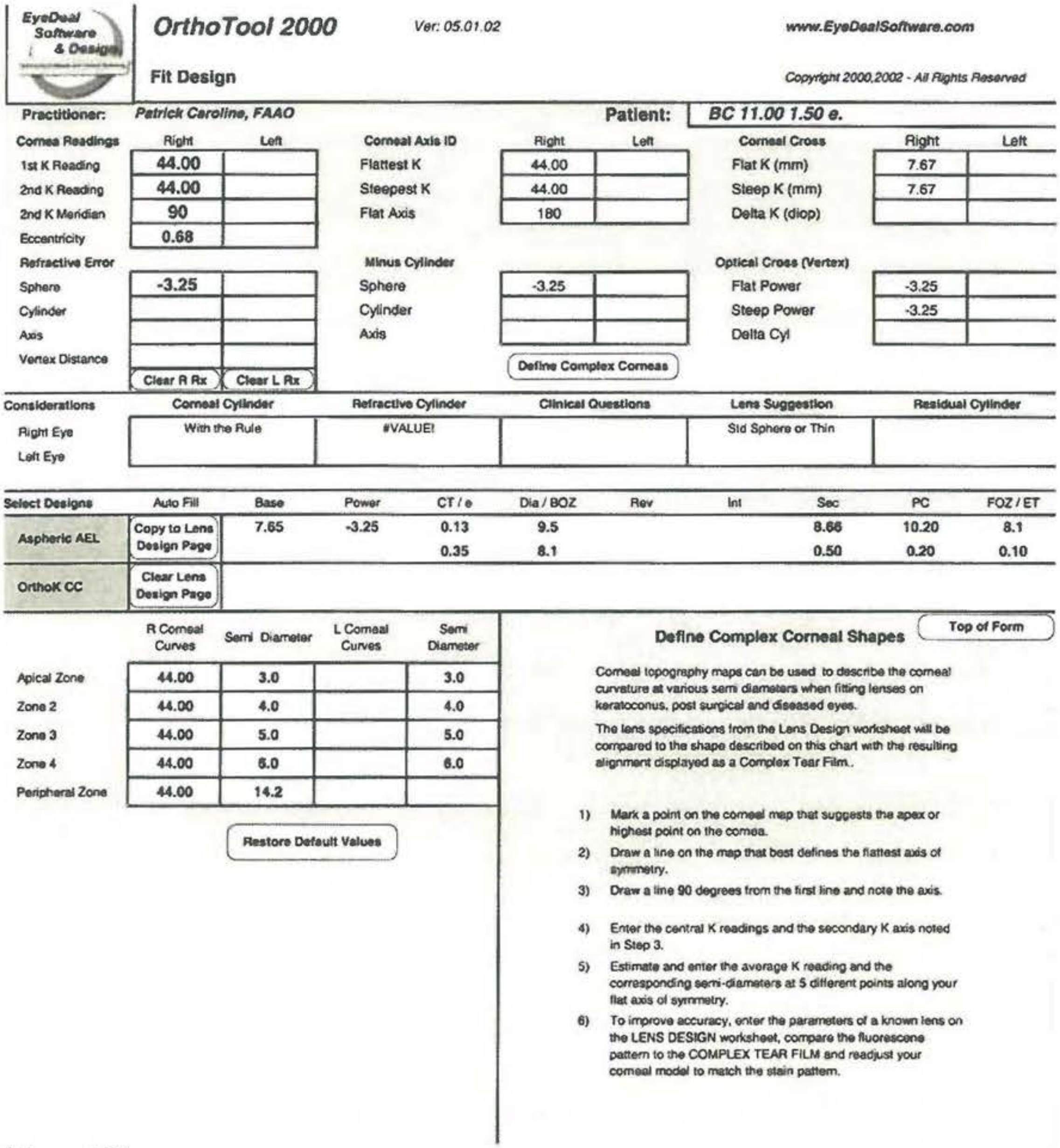
7.2 -- Baseline Topographical Mapping



(Figure 69) OD baseline topographical mappings/
Sim K: 44.40/43.80 @ 109°/19°

- mild/regular with the rule astigmatism

7.3 -- Aspheric Reverse Geometry Lens Design



EyeDeal Software & Design

OrthoTool 2000 Ver: 05.01.02 www.EyeDealSoftware.com

Fit Design

Copyright 2000,2002 - All Rights Reserved

Practitioner: Patrick Caroline, FAAO **Patient:** BC 11.00 1.50 e.

Cornea Readings	Right	Left	Corneal Axis ID	Right	Left	Corneal Cross	Right	Left
1st K Reading	44.00		Flattest K	44.00		Flat K (mm)	7.67	
2nd K Reading	44.00		Steepest K	44.00		Steep K (mm)	7.67	
2nd K Meridian	90		Flat Axis	180		Delta K (diop)		
Eccentricity	0.68							
Refractive Error			Minus Cylinder			Optical Cross (Vertex)		
Sphere	-3.25		Sphere	-3.25		Flat Power	-3.25	
Cylinder			Cylinder			Steep Power	-3.25	
Axis			Axis			Delta Cyl		
Vertex Distance								

Clear R Rx | Clear L Rx | Define Complex Corneas

Considerations	Corneal Cylinder	Refractive Cylinder	Clinical Questions	Lens Suggestion	Residual Cylinder
Right Eye	With the Rule	#VALUE!		Std Sphere or Thin	
Left Eye					

Select Designs	Auto Fill	Base	Power	CT / e	Dia / BOZ	Rev	Int	Sec	PC	FOZ / ET
Aspheric AEL	Copy to Lens Design Page	7.65	-3.25	0.13	9.5			8.66	10.20	8.1
				0.35	8.1			0.50	0.20	0.10
OrthoK CC	Clear Lens Design Page									

	R Corneal Curves	Semi Diameter	L Corneal Curves	Semi Diameter
Apical Zone	44.00	3.0		3.0
Zone 2	44.00	4.0		4.0
Zone 3	44.00	5.0		5.0
Zone 4	44.00	6.0		6.0
Peripheral Zone	44.00	14.2		

Restore Default Values

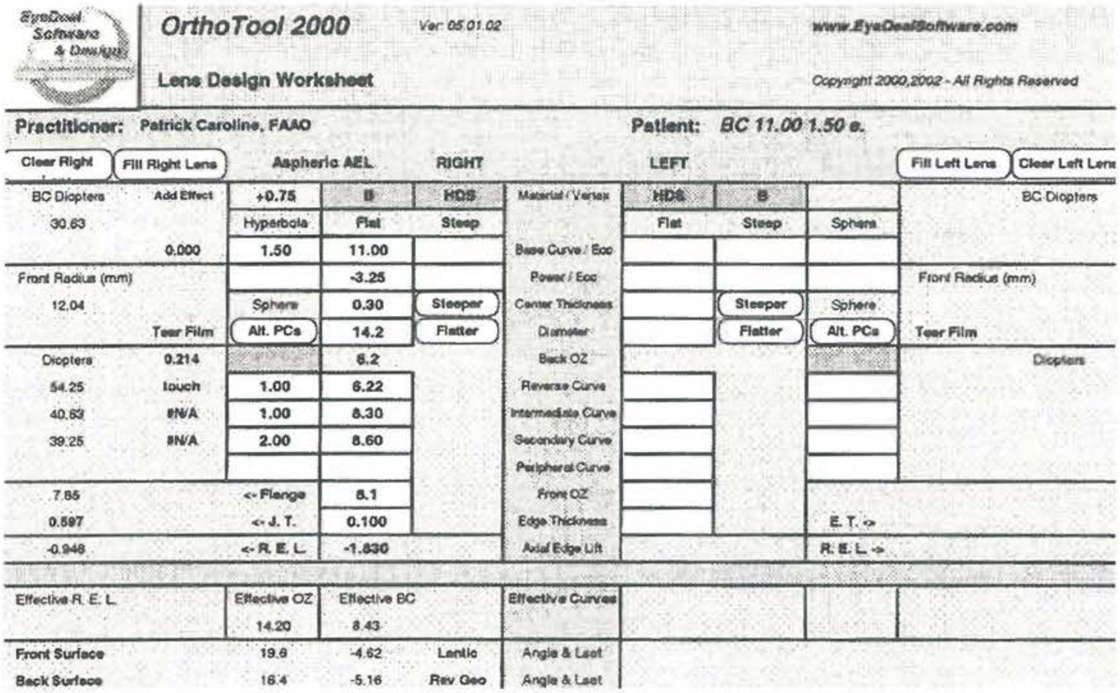
Define Complex Corneal Shapes Top of Form

Corneal topography maps can be used to describe the corneal curvature at various semi diameters when fitting lenses on keratoconus, post surgical and diseased eyes.

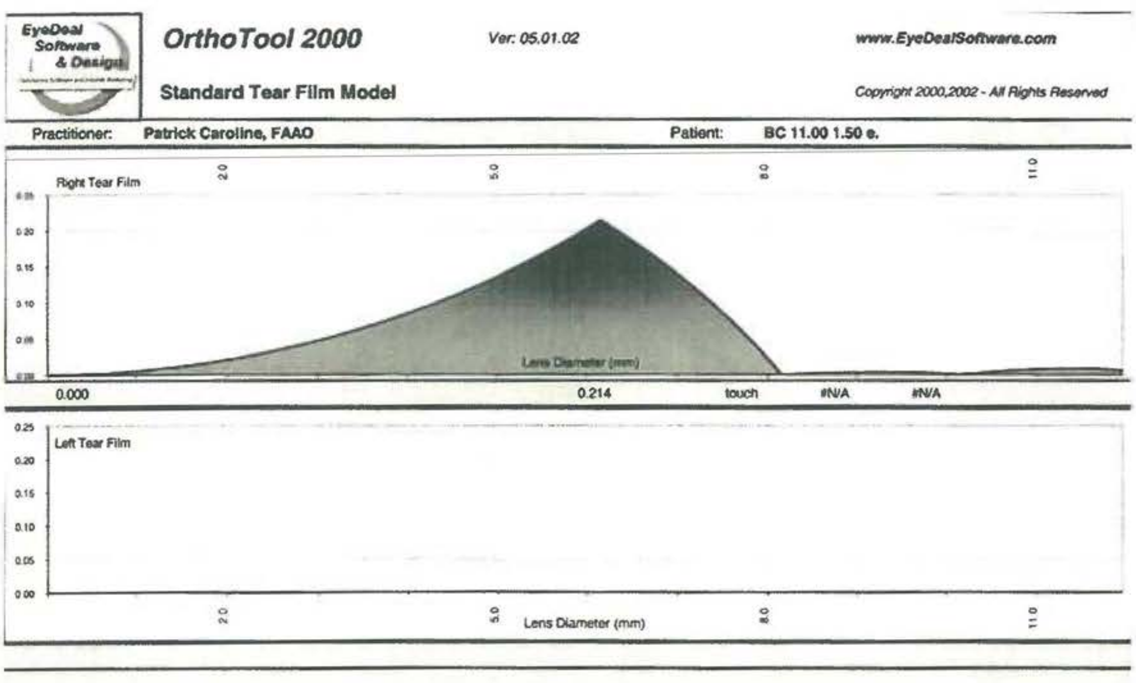
The lens specifications from the Lens Design worksheet will be compared to the shape described on this chart with the resulting alignment displayed as a Complex Tear Film.

1) Mark a point on the corneal map that suggests the apex or highest point on the cornea.
2) Draw a line on the map that best defines the flattest axis of symmetry.
3) Draw a line 90 degrees from the first line and note the axis.
4) Enter the central K readings and the secondary K axis noted in Step 3.
5) Estimate and enter the average K reading and the corresponding semi-diameters at 5 different points along your flat axis of symmetry.
6) To improve accuracy, enter the parameters of a known lens on the LENS DESIGN worksheet, compare the fluorescene pattern to the COMPLEX TEAR FILM and readjust your corneal model to match the stain pattern.

(Figure 70)

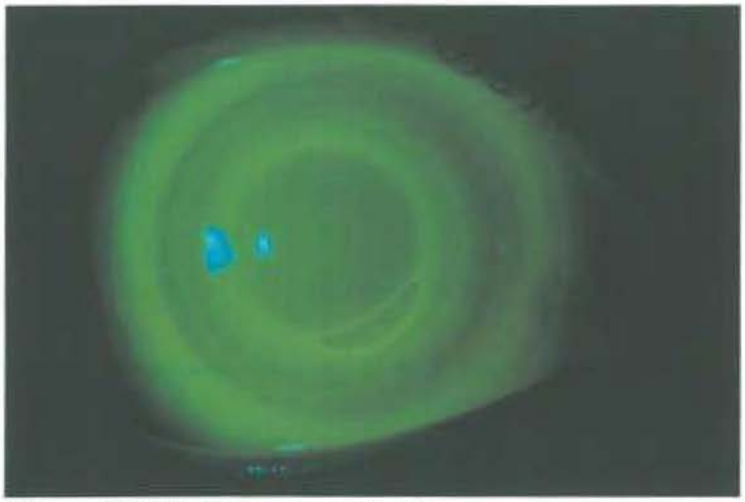


(Figure 71)



(Figure 72)

7.4 – Examination



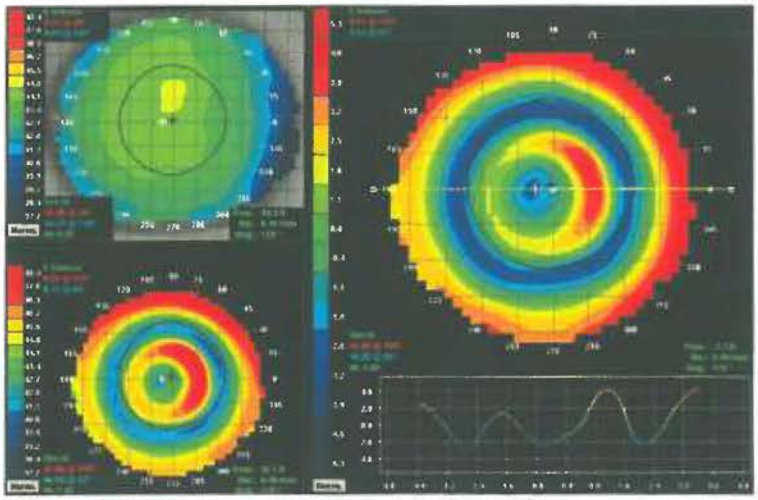
(Figure 73) OD slit lamp examination

Observations after lens fitting:

- the subject noted poor comfort
- well centered treatment zone with midperipheral bubble in reverse curve
- bubble eliminated after reablication
- blurry vision secondary of positive asphericity on the back curve
- VA= 20/25 after blinking
- 0.25mm movement in primary gaze and 0.5mm movement in up gaze
- no flutting
- good limbal coverage

Observations after ten hours of contact lens wear:

- unaided VA= 20/20
- over correction= -0.50 D



(Figure 74) OD corneal topographical mappings

- well centered central flattening with adjacent ring of steepening and midperipheral ring of flattening
- maximum central flattening: -2.37 D

Chapter 8

Pilot Study E

8.1 -- Reverse Geometry Silicone Hydrogel Contact Lenses For Overnight Wear

Start date:	October, 18th 2007 (10 PM)
Completion date:	October, 19th 2007 (8 AM)

Methods: Ten hours of overnight wear reverse geometry soft contact lenses for the reduction of myopia.

Subject: male/ 55 years old/ caucasian

Spectacle Rx OS:	-2.00 / -2.50 / 45°
Keratometry OS:	45.20/43.30 @ 71°/161°
Spectacle VA OS:	20/60
Unaided VA:	20/200

Contact Lens Parameters:

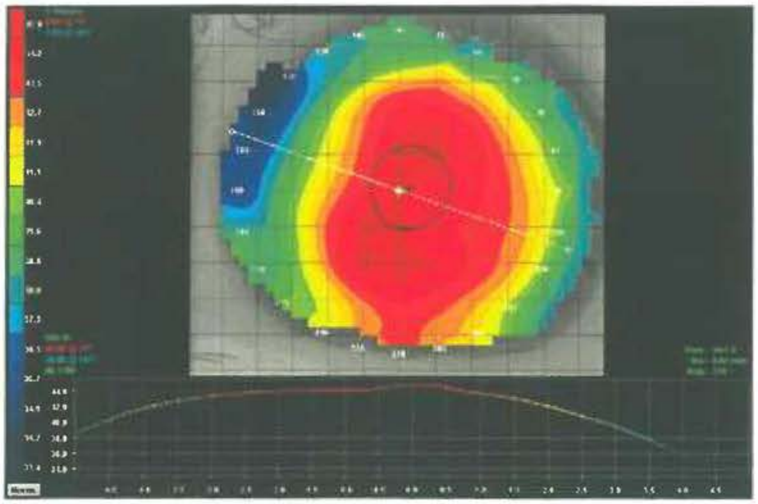
Base curve:	11.00 mm
Diameter:	14.2 mm
Power:	-3.25 D
Optic zone diameter:	6.22 mm
Eccentricity:	1.5

Material:	Benz hioxifilcon A
Water content:	59%
Oxygen permeability (DK):	21

Contact Lens Manufacturer: MedLens Innovations, Inc.
1325 Progress Drive
Front Royal, Virginia 22630

Conclusions: Increased flattening of the central base curve beyond the 8.50, as would be calculated to reduce the amount of the subject myopia in a rigid lens, to 11.00 does not appear to create an effective treatment zone.

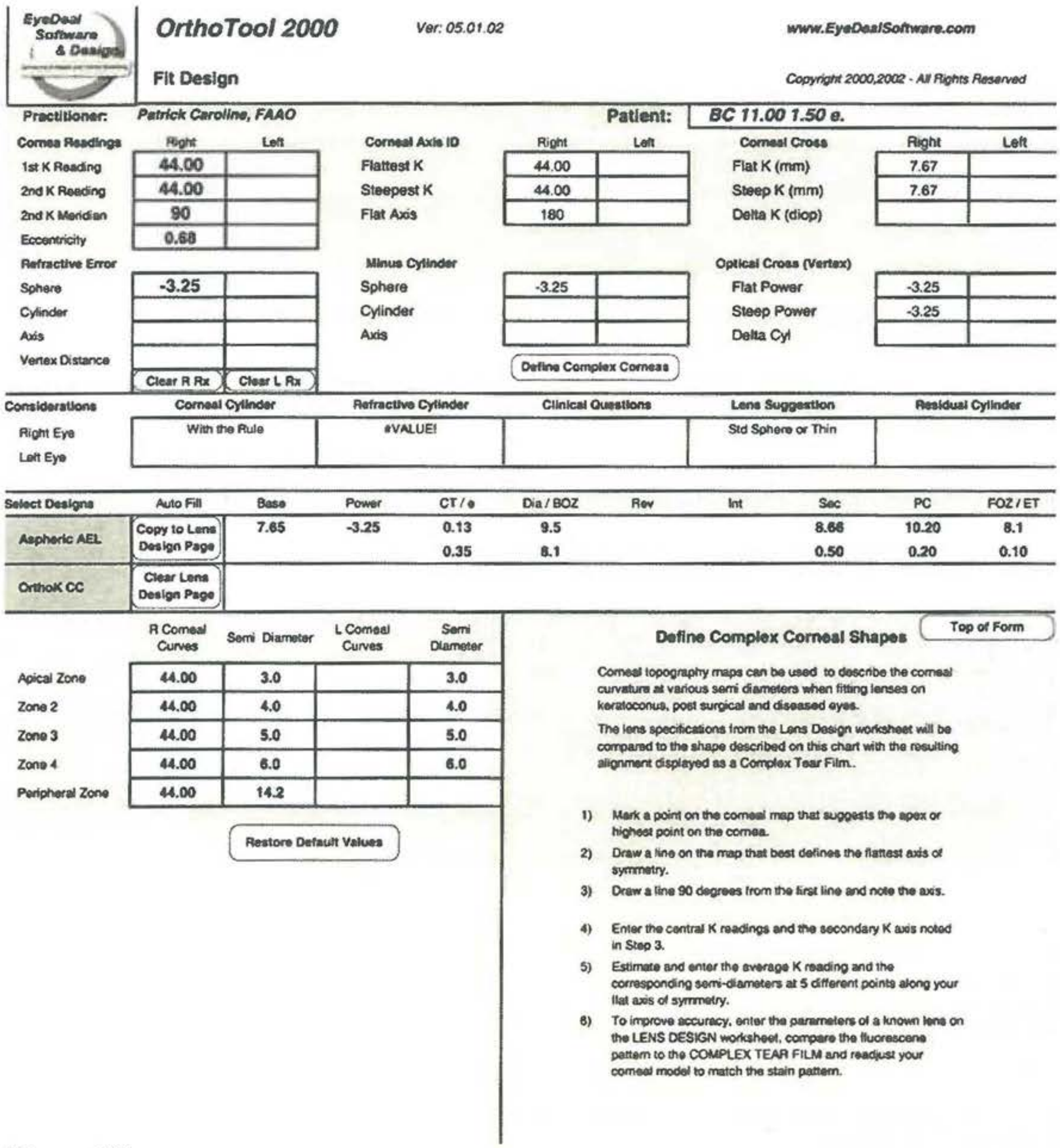
8.2 -- Baseline Topographical Mapping



(Figure 75) OS baseline topographical mapping
Sim K: 45.20/43.30 @ 71°/161°

- significant with the rule astigmatism

8.3 – Aspheric Reverse Geometry Lens Design


EyeDeal Software & Design

OrthoTool 2000 Ver: 05.01.02 www.EyeDealSoftware.com

Fit Design

Practitioner: Patrick Caroline, FAAO **Patient:** BC 11.00 1.50 e.

Cornea Readings	Right	Left	Corneal Axis ID	Right	Left	Corneal Cross	Right	Left
1st K Reading	44.00		Flattest K	44.00		Flat K (mm)	7.67	
2nd K Reading	44.00		Steepest K	44.00		Steep K (mm)	7.67	
2nd K Meridian	90		Flat Axis	180		Delta K (diop)		
Eccentricity	0.68							

Refractive Error	Right	Left	Minus Cylinder	Right	Left	Optical Cross (Vertex)	Right	Left
Sphere	-3.25		Sphere	-3.25		Flat Power	-3.25	
Cylinder			Cylinder			Steep Power	-3.25	
Axis			Axis			Delta Cyl		
Vertex Distance								

Clear R Rx | Clear L Rx | Define Complex Corneas

Considerations	Corneal Cylinder	Refractive Cylinder	Clinical Questions	Lens Suggestion	Residual Cylinder
Right Eye	With the Rule	#VALUE!		Std Sphere or Thin	
Left Eye					

Select Designs	Auto Fill	Base	Power	CT / e	Dia / BOZ	Rev	Int	Sec	PC	FOZ / ET
Aspheric AEL	Copy to Lens Design Page	7.65	-3.25	0.13	9.5			8.68	10.20	8.1
				0.35	8.1			0.50	0.20	0.10
OrthoK CC	Clear Lens Design Page									

	R Corneal Curves	Semi Diameter	L Corneal Curves	Semi Diameter
Apical Zone	44.00	3.0		3.0
Zone 2	44.00	4.0		4.0
Zone 3	44.00	5.0		5.0
Zone 4	44.00	6.0		6.0
Peripheral Zone	44.00	14.2		

Restore Default Values

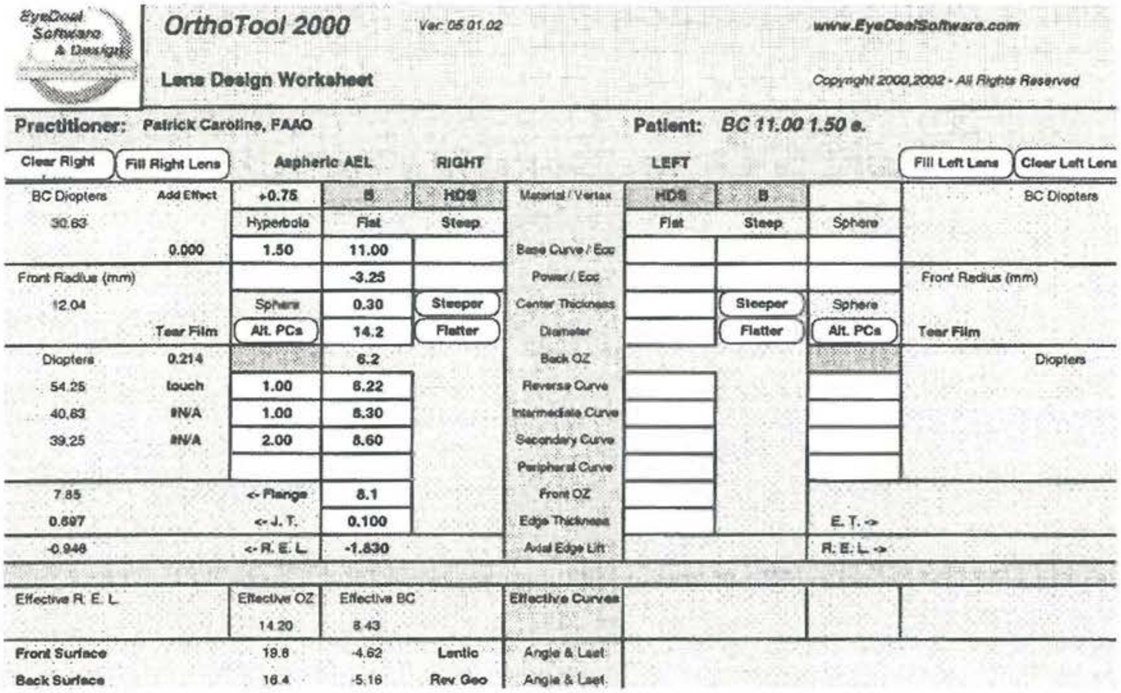
Define Complex Corneal Shapes Top of Form

Corneal topography maps can be used to describe the corneal curvature at various semi diameters when fitting lenses on keratoconus, post surgical and diseased eyes.

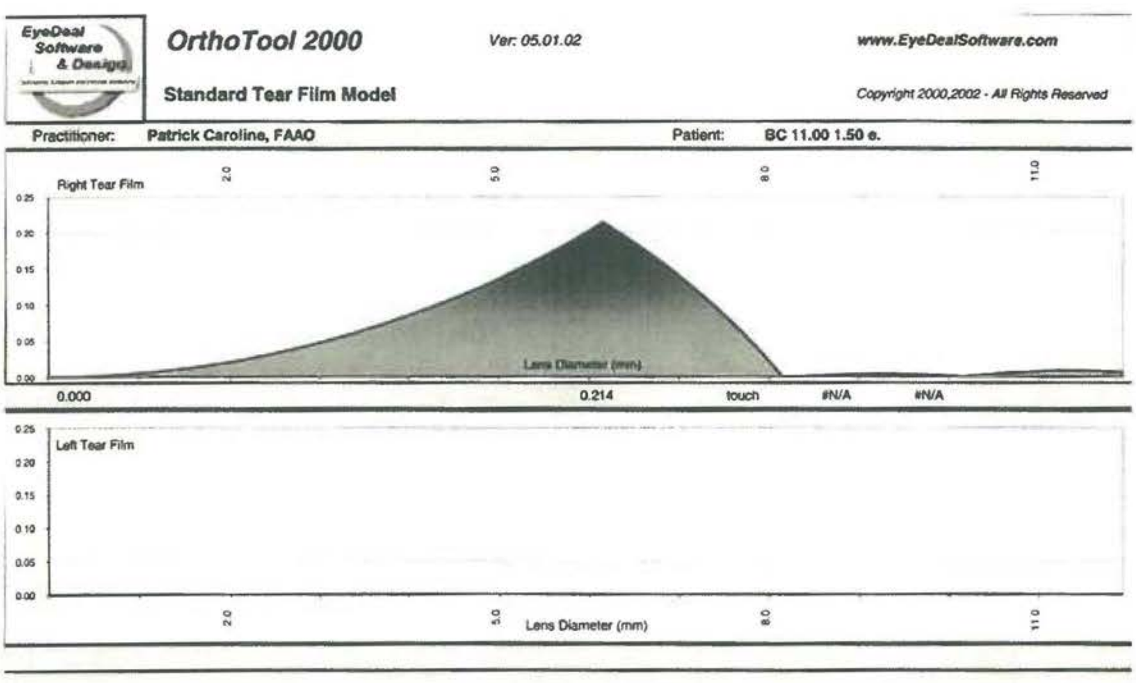
The lens specifications from the Lens Design worksheet will be compared to the shape described on this chart with the resulting alignment displayed as a Complex Tear Film.

1) Mark a point on the corneal map that suggests the apex or highest point on the cornea.
2) Draw a line on the map that best defines the flattest axis of symmetry.
3) Draw a line 90 degrees from the first line and note the axis.
4) Enter the central K readings and the secondary K axis noted in Step 3.
5) Estimate and enter the average K reading and the corresponding semi-diameters at 5 different points along your flat axis of symmetry.
6) To improve accuracy, enter the parameters of a known lens on the LENS DESIGN worksheet, compare the fluorescene pattern to the COMPLEX TEAR FILM and readjust your corneal model to match the stain pattern.

(Figure 76)

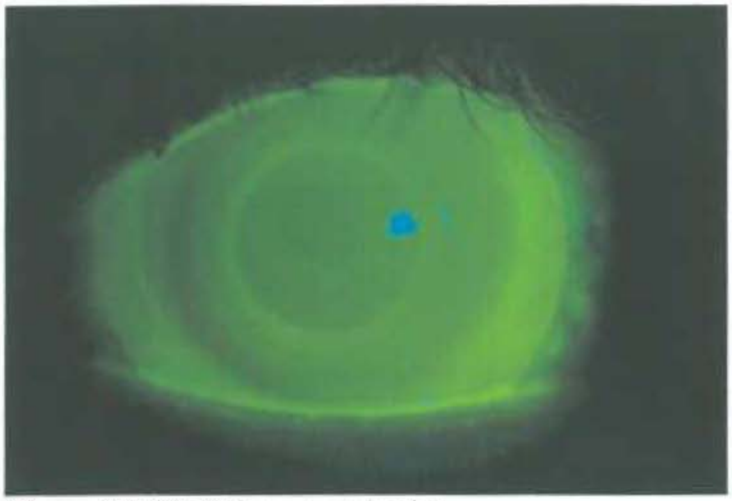


(Figure 77)



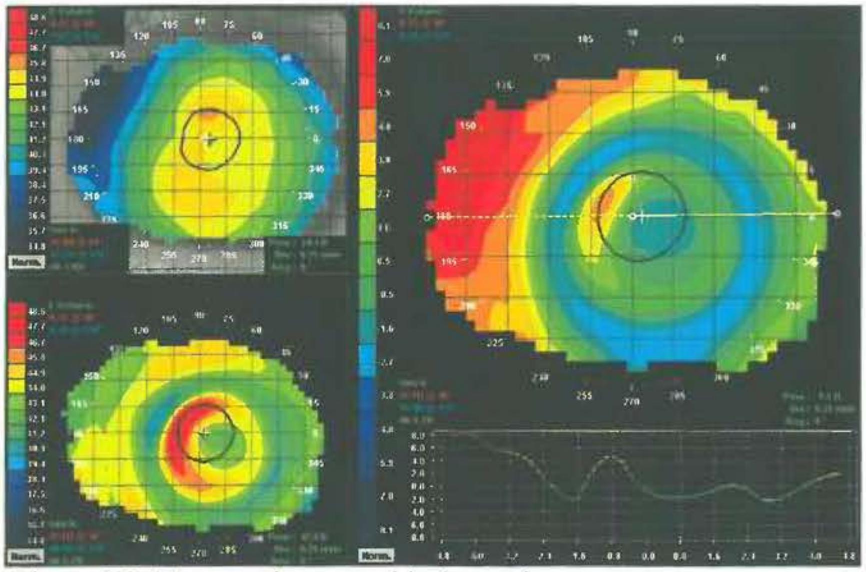
(Figure 78)

8.4 -- Examination



(Figure 79) OS slit lamp examination

- well centered treatment zone with mid peripheral relief zone
- 0.25mm movement in primary gaze and 0.5mm movement in up gaze
- good limbal coverage
- no flutting
- no bubbles



(Figure 80) OS corneal topographical mapping

- slightly temporal centered central flattening with adjacent ring of steepening and midperipheral ring of flattening
- maximum central flattening: -1.50 D

- corneal topography image was decentred but the lens was not
  → subject secondary to poor fixation on the topographer secondary to amblyopia

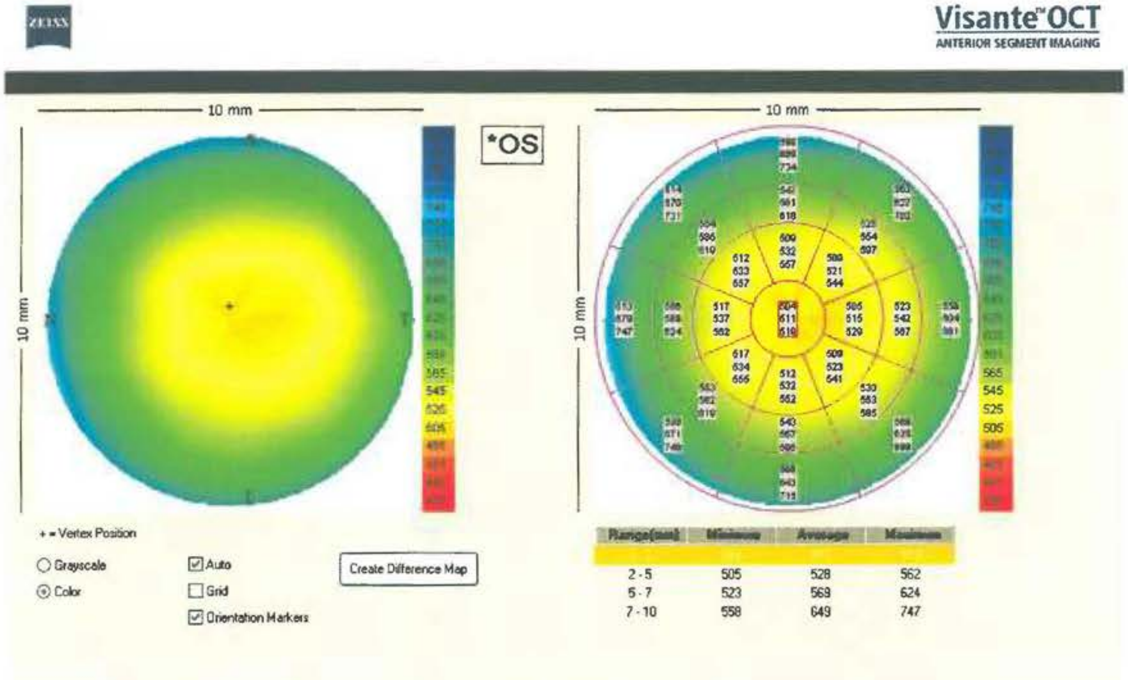
Slit lamp examination after overnight wear:

- no contact lens movement
- eye looks quiet and nice
- well-centred treatment zone

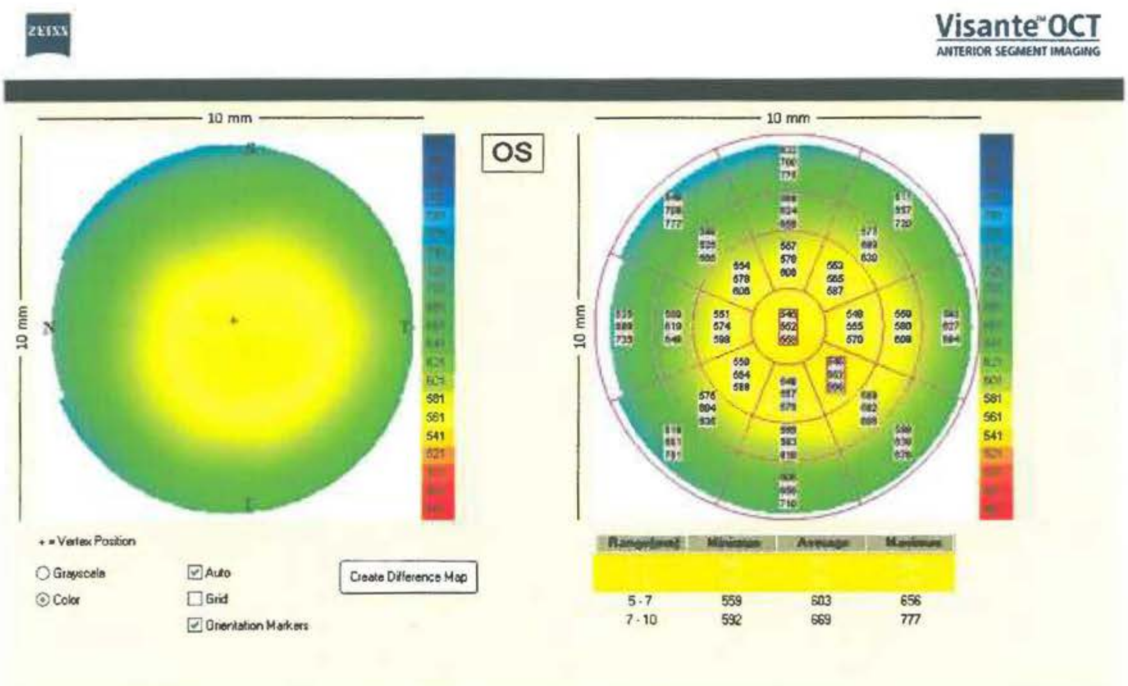
Subjective symptoms after overnight wear:

- mild foreign body sensation under the upper lid

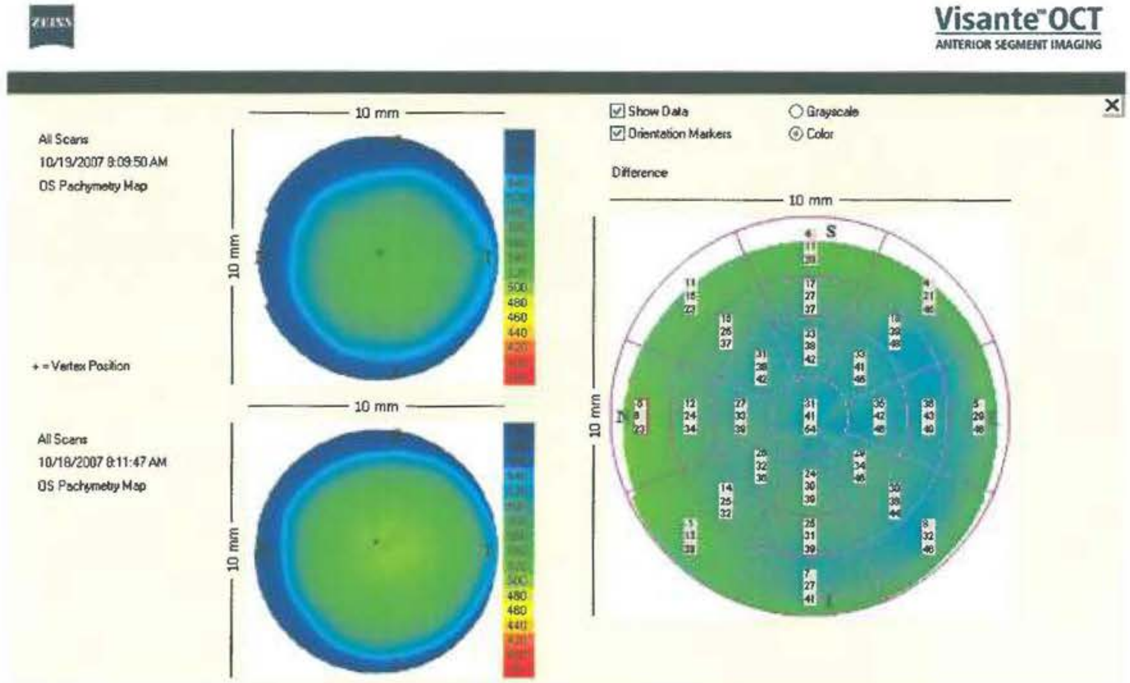
8.5 – Corneal Thickness Difference Displays



(Figure 81) Corneal thickness mapping OS (baseline)



(Figure 82) Corneal thickness mapping OS (after overnight wear)



(Figure 83) Corneal difference mapping OS

Result:

- Corneal swelling ≈ 40 microns (before: 510/ after: 550)

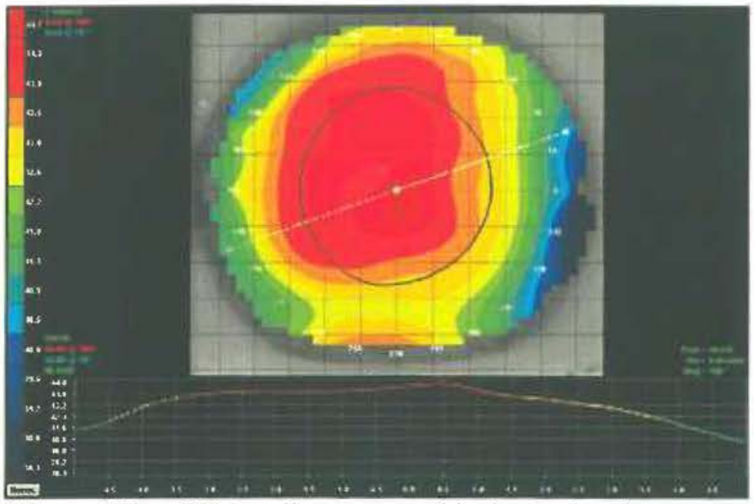
Chapter 9

Pilot Study F

9.1 -- Reverse Geometry Silicone Hydrogel Contact Lenses For Daily Wear

Start date:	November, 8th 2007 (8 AM)	
Completion date:	November, 8th 2007 (4 PM)	
Methods:	Eight hours of daily wear reverse geometry soft contact lenses for the reduction of myopia.	
Subject:	male/ 26 years old/ caucasian	
	Spectacle Rx OD:	-3.25 DS
	Keratometry OD:	44.00/44.50 @ 11°/101°
	Spectacle VA OD:	20/15
	Unaided VA OD:	20/400
Contact Lens Parameters:	Base curve:	11.00 mm
	Diameter:	14.2 mm
	Power:	-3.25 D
	Optic zone diameter:	1.7 mm
	Reverse curve:	7.74
	Material:	Benz hioxifilcon A
	Water content: 59%	
	Oxygen permeability (DK): 21	
Contact Lens Manufacturer:	MedLens Innovations, Inc. 1325 Progress Drive Front Royal, Virginia 22630	
Conclusions:	The grossly flat 11.00mm central base curve yielded significant central corneal flattening with ceco central corneal steepening, greater nasally, when worn daily. This is suspected to be secondary to the amount of central alignment and radial departure of the central base curve of the contact lens away from the cornea creating significant posterior lens tear film yielding a significant pull force beneath that portion of the contact lens.	

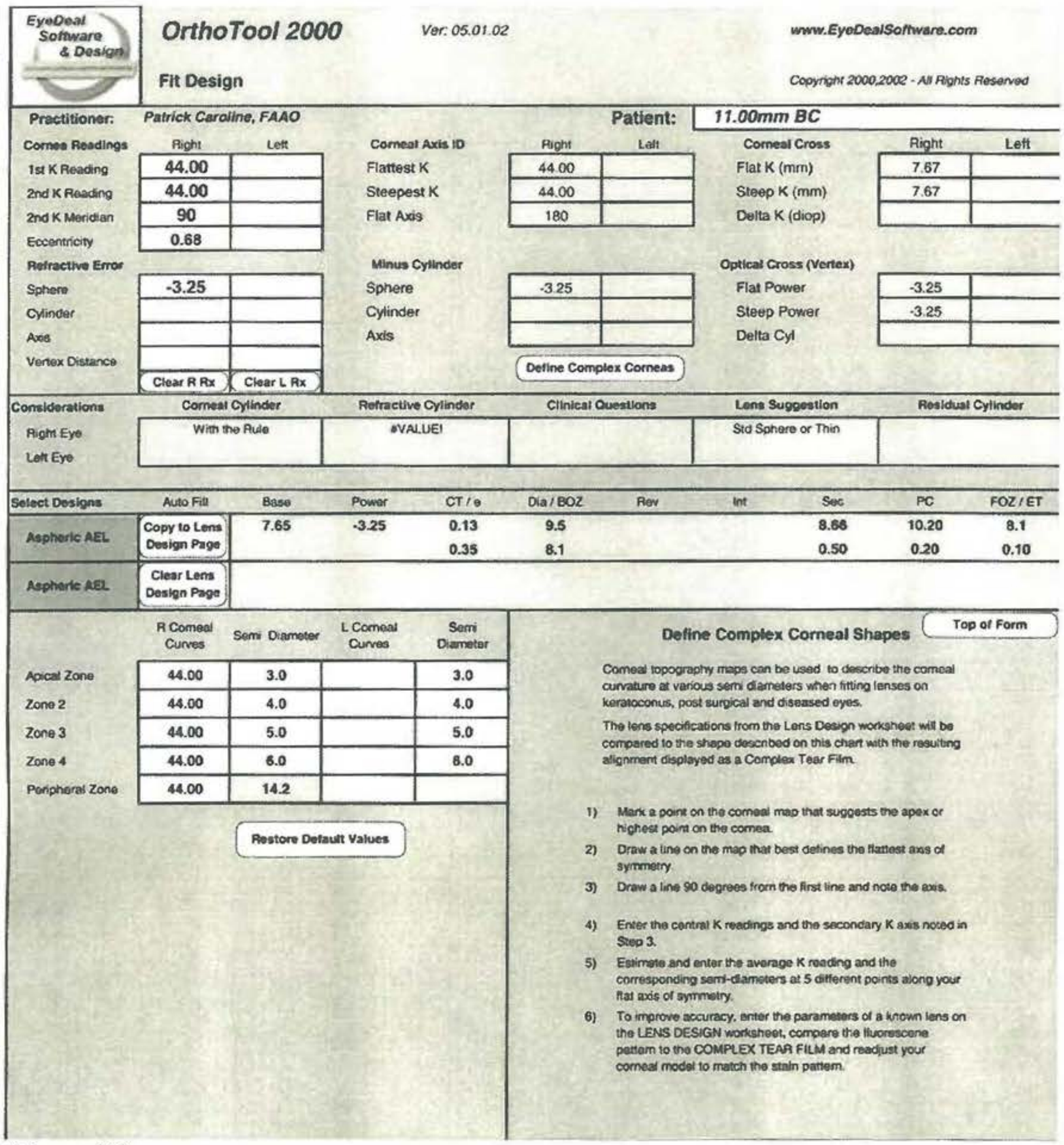
9.2 – Baseline Topographical Mapping



(Figure 84) OD baseline topographical mappings/
Sim K: 44.40/43.80 @ 109°/19°

- mild/regular with the rule astigmatism

9.3 -- Aspheric Reverse Geometry Lens Design



EyeDeal Software & Design — **OrthoTool 2000** — Ver: 05.01.02 — www.EyeDealSoftware.com

Fit Design — Copyright 2000,2002 - All Rights Reserved

Practitioner: Patrick Caroline, FAAO — **Patient:** 11.00mm BC

Cornea Readings	Right	Left	Corneal Axis ID	Right	Left	Corneal Cross	Right	Left
1st K Reading	44.00		Flattest K	44.00		Flat K (mm)	7.67	
2nd K Reading	44.00		Steepest K	44.00		Steep K (mm)	7.67	
2nd K Meridian	90		Flat Axis	180		Delta K (diop)		
Eccentricity	0.68							
Refractive Error			**Minus Cylinder**			**Optical Cross (Vertex)**		
Sphere	-3.25		Sphere	-3.25		Flat Power	-3.25	
Cylinder			Cylinder			Steep Power	-3.25	
Axis			Axis			Delta Cyl		
Vertex Distance								

Clear R Rx — Clear L Rx — Define Complex Corneas

Considerations	Corneal Cylinder	Refractive Cylinder	Clinical Questions	Lens Suggestion	Residual Cylinder
Right Eye	With the Rule	#VALUE!		Std Sphere or Thin	
Left Eye					

Select Designs	Auto Fill	Base	Power	CT / e	Dia / BOZ	Rev	Int	Sec	PC	FOZ / ET
Aspheric AEL	Copy to Lens Design Page	7.65	-3.25	0.13	9.5			8.66	10.20	8.1
				0.35	8.1			0.50	0.20	0.10
Aspheric AEL	Clear Lens Design Page									

	R Corneal Curves	Semi Diameter	L Corneal Curves	Semi Diameter
Apical Zone	44.00	3.0		3.0
Zone 2	44.00	4.0		4.0
Zone 3	44.00	5.0		5.0
Zone 4	44.00	6.0		6.0
Peripheral Zone	44.00	14.2		

Restore Default Values

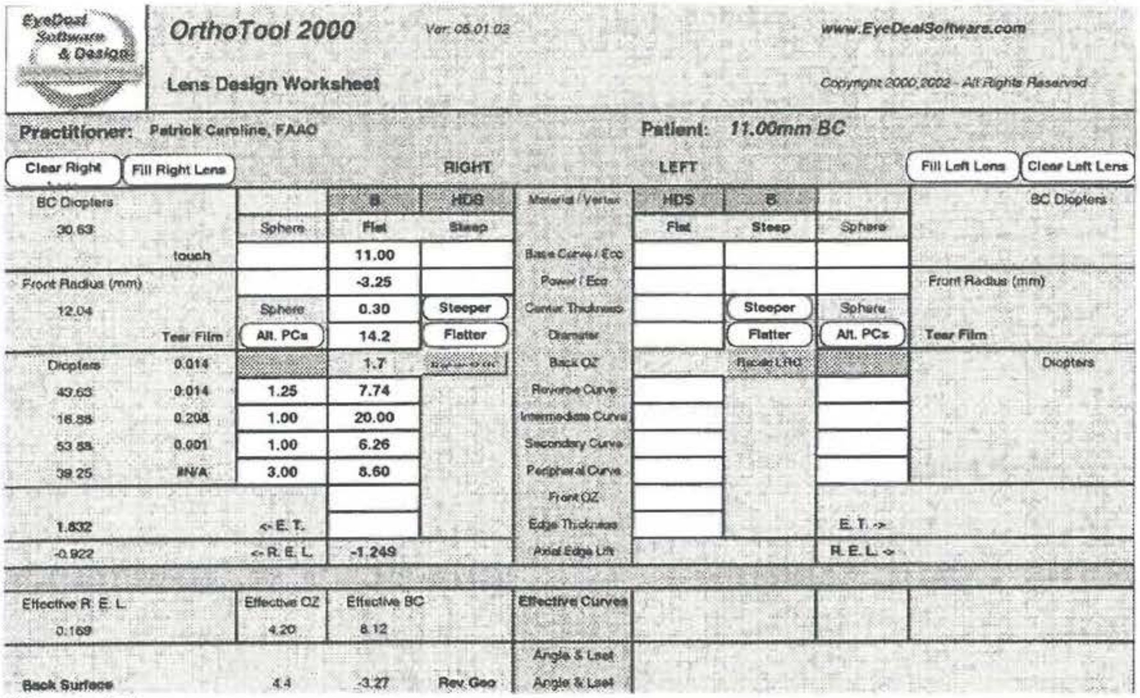
Define Complex Corneal Shapes — Top of Form

Corneal topography maps can be used to describe the corneal curvature at various semi diameters when fitting lenses on keratoconus, post surgical and diseased eyes.

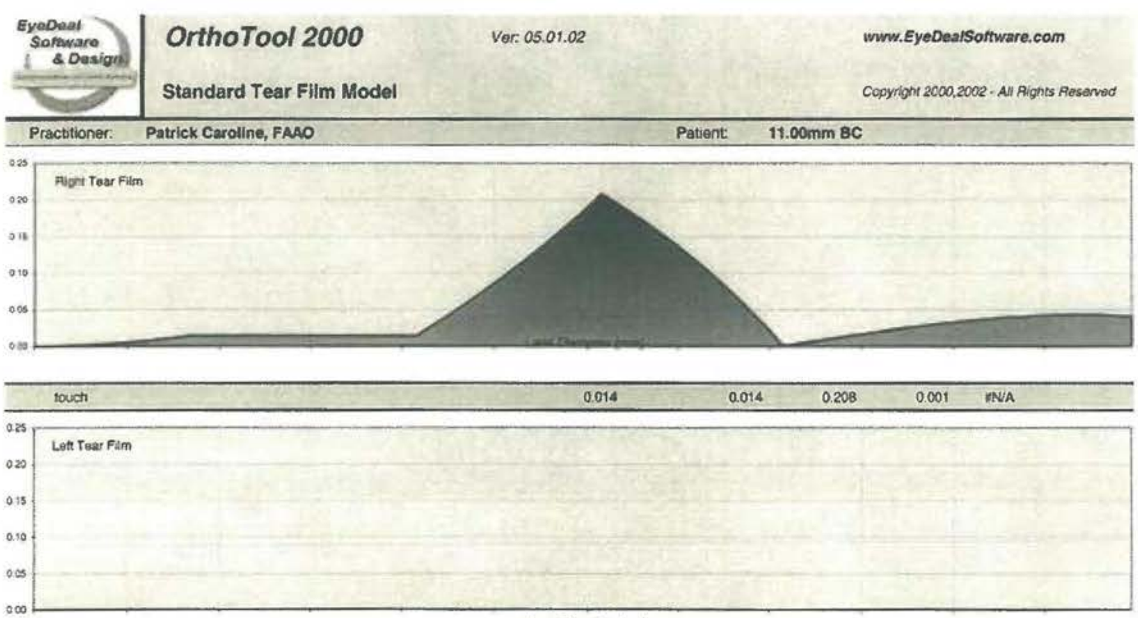
The lens specifications from the Lens Design worksheet will be compared to the shape described on this chart with the resulting alignment displayed as a Complex Tear Film.

1) Mark a point on the corneal map that suggests the apex or highest point on the cornea.
2) Draw a line on the map that best defines the flattest axis of symmetry.
3) Draw a line 90 degrees from the first line and note the axis.
4) Enter the central K readings and the secondary K axis noted in Step 3.
5) Estimate and enter the average K reading and the corresponding semi-diameters at 5 different points along your flat axis of symmetry.
6) To improve accuracy, enter the parameters of a known lens on the LENS DESIGN worksheet, compare the fluorescene pattern to the COMPLEX TEAR FILM and readjust your corneal model to match the stain pattern.

(Figure 85)

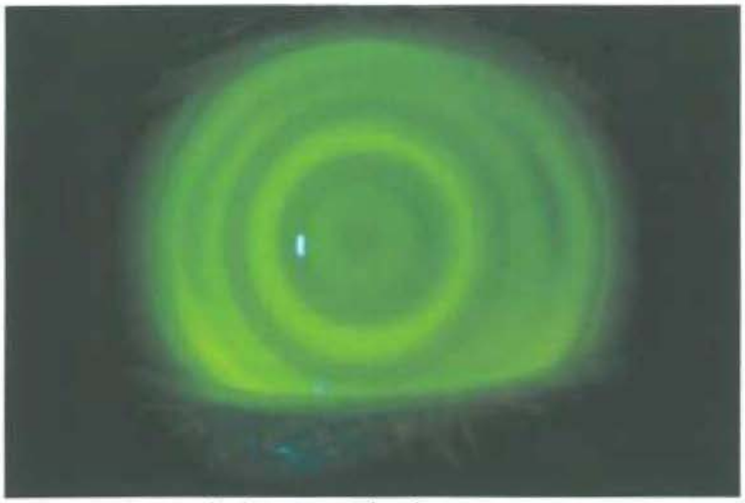


(Figure 86)



(Figure 87)

9.4 -- Examination



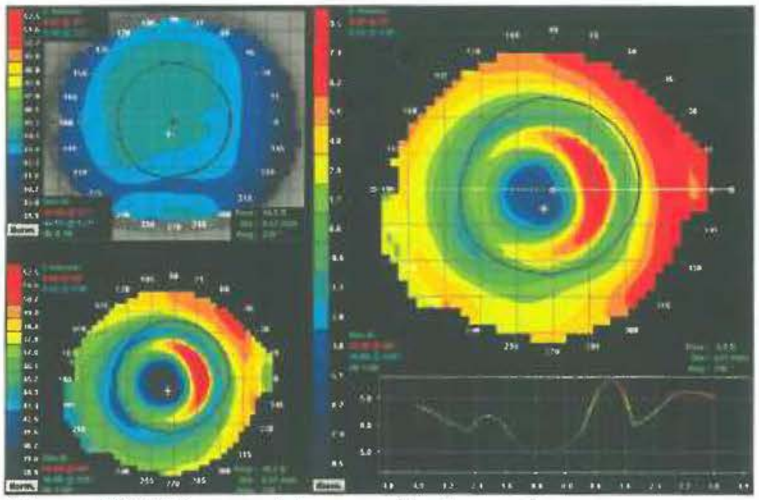
(Figure 88) OD slit lamp examination

- well centered treatment zone with mid peripheral relief zone
- 0.25mm movement in primary gaze and 0.5mm movement in up gaze
- good limbal coverage
- no flutting
- no bubbles

- unaided VA: 20/200
- spectacle VA: 20/50 → secondary to the small optic zone diameter

Subjective symptoms after contact lens fitting:

- foreign body sensation
- uncomfortable



(Figure 89) OD corneal topographical mapping

- topographical changes were created
- well centered treatment zone with ring of mid-peripheral steepening and area temporal to center of steepening within treatment zone with adjacent area of nasal flattening
- maximum central flattening: -5.87 D

Slit lamp examination after eight hour daily wear:

- no contact lens movement
- well-centred
- trace injection nasally

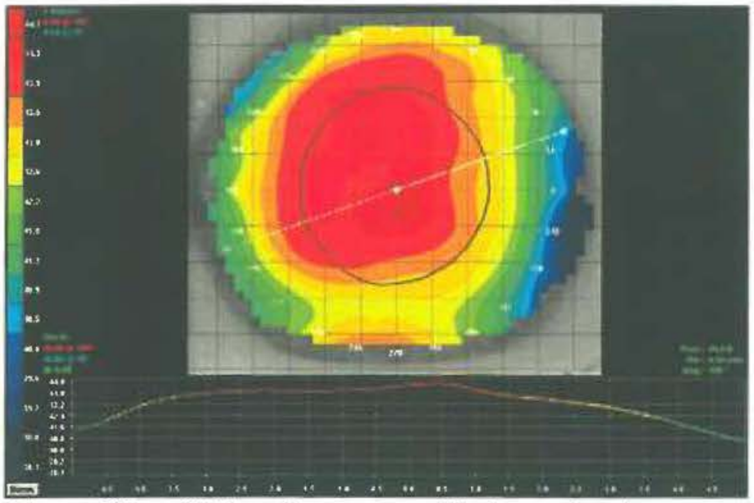
Chapter 10

Pilot Study G

10.1 -- Reverse Geometry Silicone Hydrogel Contact Lenses For Daily Wear

Start date:	November, 26th 2007 (9 AM)	
Completion date:	November, 26th 2007 (5 PM)	
Methods:	Eight hours of daily wear reverse geometry soft contact lenses for the reduction of myopia.	
Subject:	male/ 26 years old/ caucasian	
	Spectacle Rx OD:	-3.25 DS
	Keratometry OD:	44.00/44.50 @ 11°/101°
	Spectacle VA OD:	20/15
	Unaided VA OD:	20/400
Contact Lens Parameters:	Base curve:	8.45 mm
	Diameter:	14.2 mm
	Power:	-3.25 D
	Optic zone diameter:	1.7 mm
	Reverse curve:	8.05 mm
	Material:	Benz hioxifilcon A
	Water content:	59%
	Oxygen permeability (DK):	21
Contact Lens Manufacturer:	MedLens Innovations, Inc. 1325 Progress Drive Front Royal, Virginia 22630	
Conclusions:	Daily wear with this reverse geometry contact lens the central base curve of 8.45mm yielded significant central corneal flattening with ceco-central corneal steepening, greater nasally. This topographical change is suspected to be secondary to the amount of central alignment/contact of the center of the lens with the cornea and subsequent radical departure of the contact lens away from the cornea creating significant posterior lens tear film yielding a significant pull force beneath that portion of the contact lens (Figure 95)	

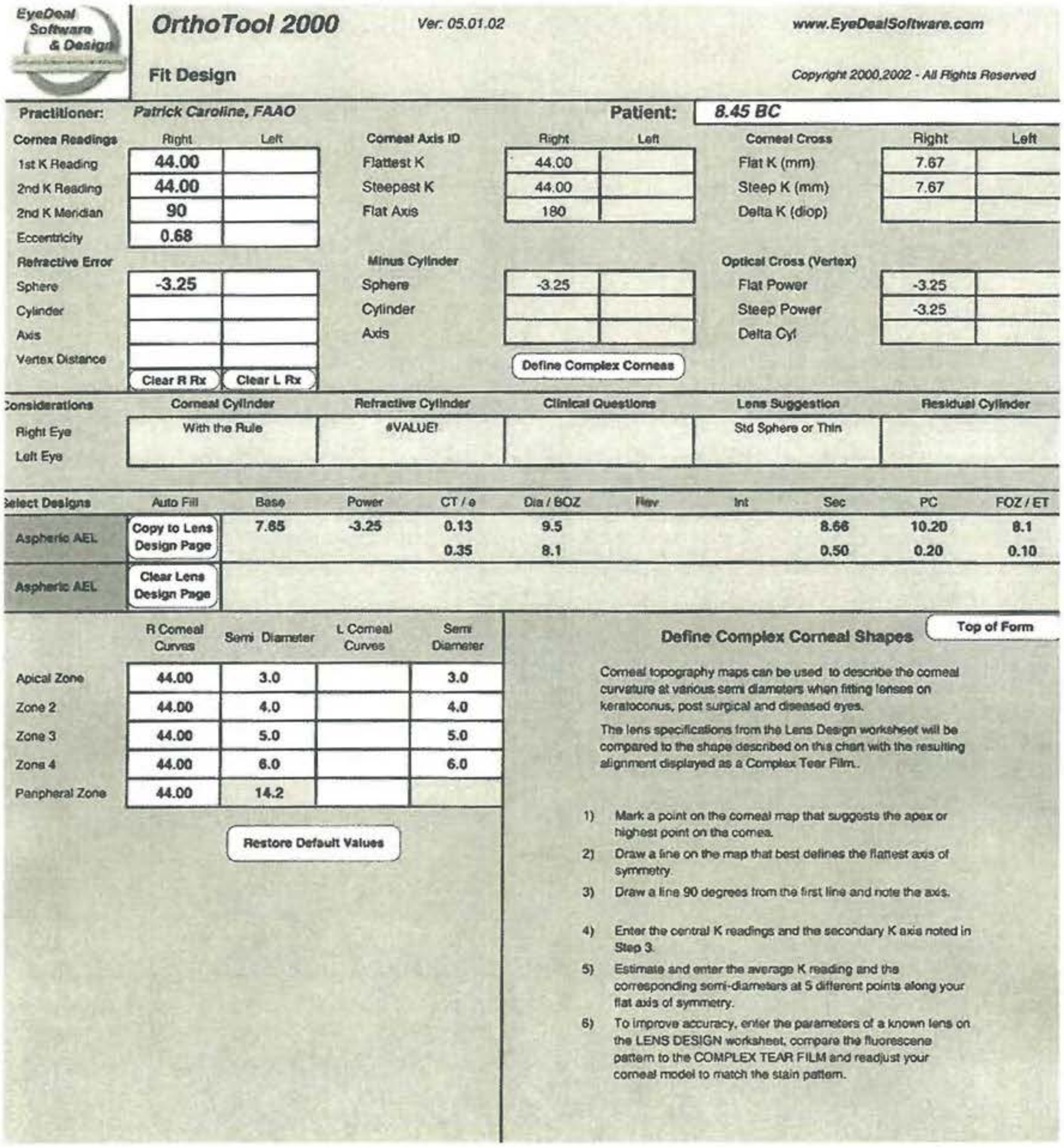
10.2 -- Baseline Topographical Mapping



(Figure 90) OD baseline topographical mappings/
Sim K: 44.40/43.80 @ 109°/19°

- mild/regular with the rule astigmatism

10.3 -- Aspheric Reverse Geometry Lens Design



EyeDeal Software & Design

OrthoTool 2000 Ver: 05.01.02 www.EyeDealSoftware.com

Fit Design Copyright 2000,2002 - All Rights Reserved

Practitioner: Patrick Caroline, FAAO Patient: 8.45 BC

Cornea Readings	Right	Left	Corneal Axis ID	Right	Left	Corneal Cross	Right	Left
1st K Reading	44.00		Flattest K	44.00		Flat K (mm)	7.67	
2nd K Reading	44.00		Steepest K	44.00		Steep K (mm)	7.67	
2nd K Meridian	90		Flat Axis	180		Delta K (diop)		
Eccentricity	0.68							
Refractive Error			Minus Cylinder			Optical Cross (Vertex)		
Sphere	-3.25		Sphere	-3.25		Flat Power	-3.25	
Cylinder			Cylinder			Steep Power	-3.25	
Axis			Axis			Delta Cyl		
Vertex Distance								

Clear R Rx | Clear L Rx | Define Complex Corneas

Considerations	Corneal Cylinder	Refractive Cylinder	Clinical Questions	Lens Suggestion	Residual Cylinder
Right Eye	With the Rule	#VALUE!		Std Sphere or Thin	
Left Eye					

Select Designs	Auto Fill	Base	Power	CT / e	Dia / BOZ	Rev	Int	Sec	PC	FOZ / ET
Aspheric AEL	Copy to Lens Design Page	7.65	-3.25	0.13	9.5			8.66	10.20	8.1
				0.35	8.1			0.50	0.20	0.10
Aspheric AEL	Clear Lens Design Page									

	R Corneal Curves	Semi Diameter	L Corneal Curves	Semi Diameter
Apical Zone	44.00	3.0		3.0
Zone 2	44.00	4.0		4.0
Zone 3	44.00	5.0		5.0
Zone 4	44.00	6.0		6.0
Peripheral Zone	44.00	14.2		

Restore Default Values

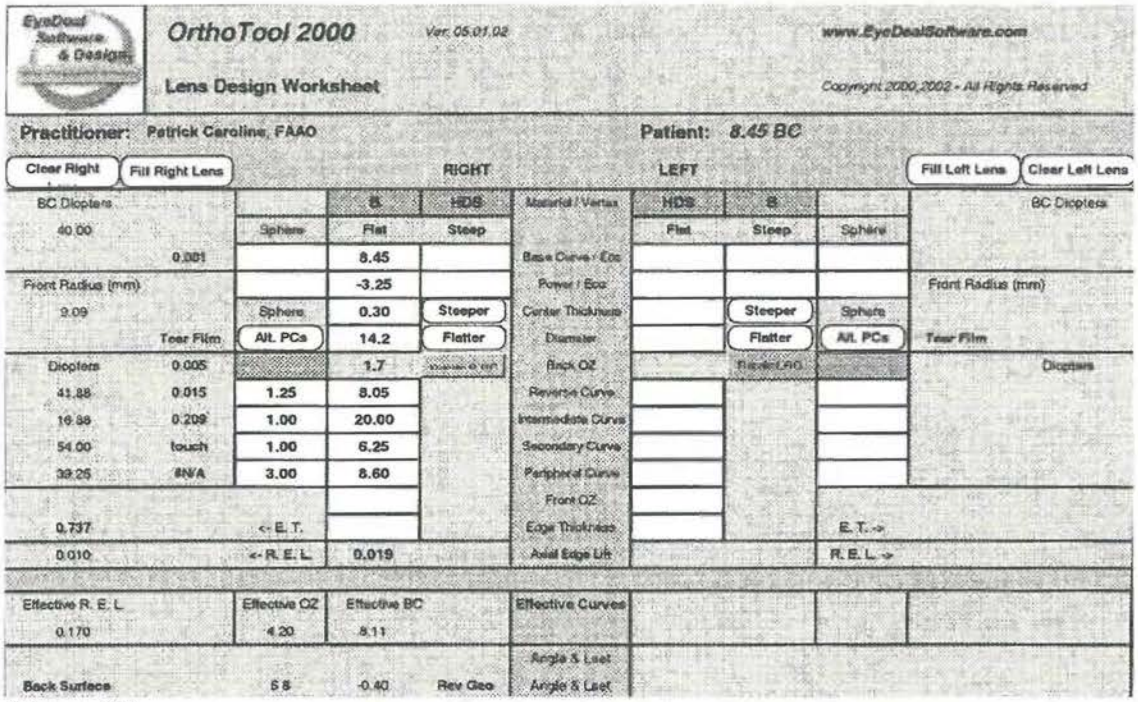
Define Complex Corneal Shapes Top of Form

Corneal topography maps can be used to describe the corneal curvature at various semi diameters when fitting lenses on keratoconus, post surgical and diseased eyes.

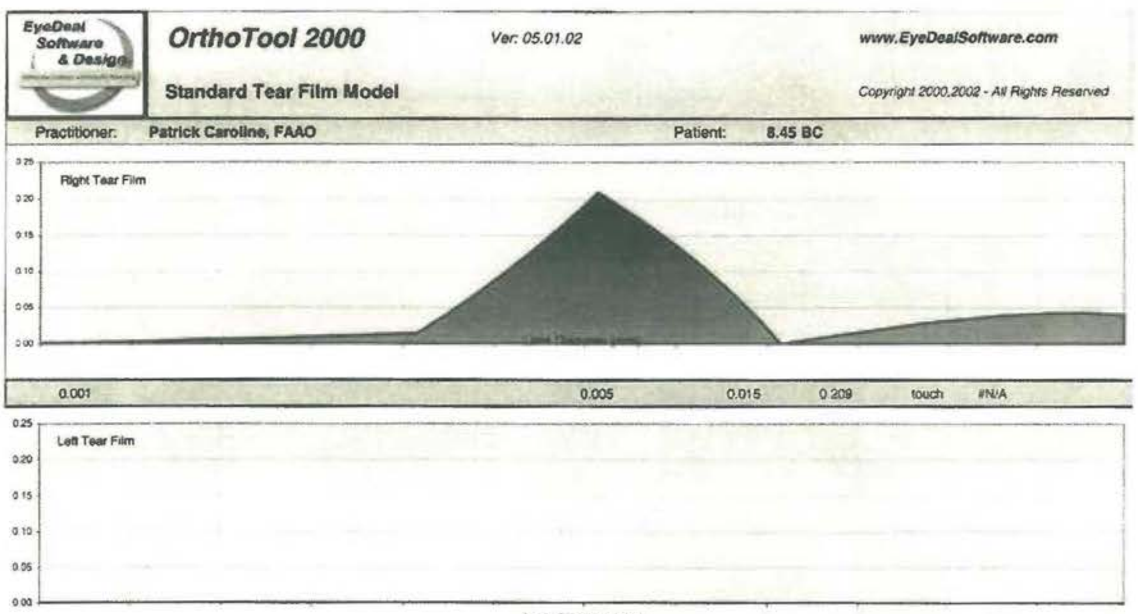
The lens specifications from the Lens Design worksheet will be compared to the shape described on this chart with the resulting alignment displayed as a Complex Tear Film.

1) Mark a point on the corneal map that suggests the apex or highest point on the cornea.
2) Draw a line on the map that best defines the flattest axis of symmetry.
3) Draw a line 90 degrees from the first line and note the axis.
4) Enter the central K readings and the secondary K axis noted in Step 3.
5) Estimate and enter the average K reading and the corresponding semi-diameters at 5 different points along your flat axis of symmetry.
6) To improve accuracy, enter the parameters of a known lens on the LENS DESIGN worksheet, compare the fluorescene pattern to the COMPLEX TEAR FILM and readjust your corneal model to match the stain pattern.

(Figure 91)

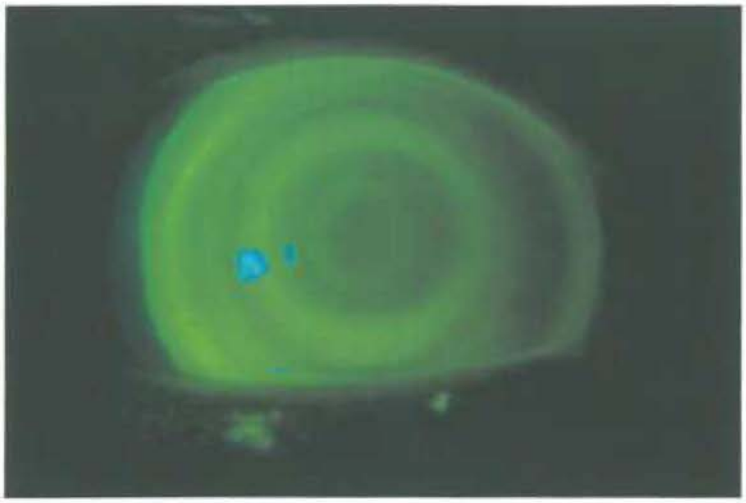


(Figure 92)



(Figure 93)

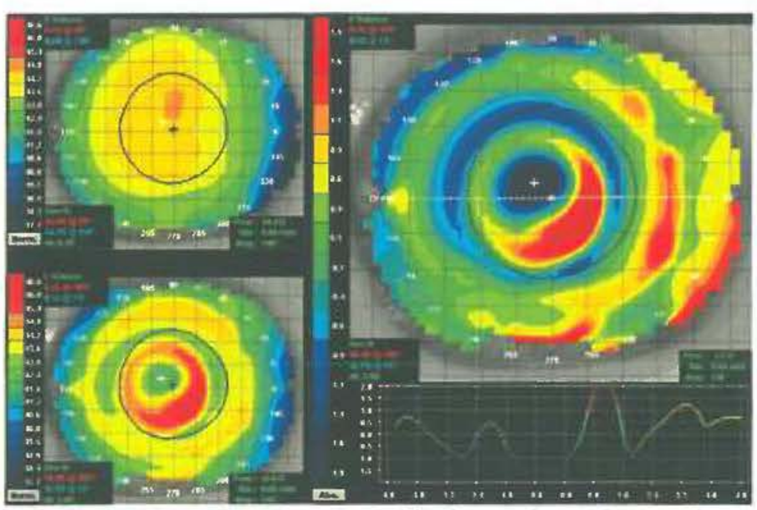
10.4 -- Examination



(Figure 94) OD slit lamp examination

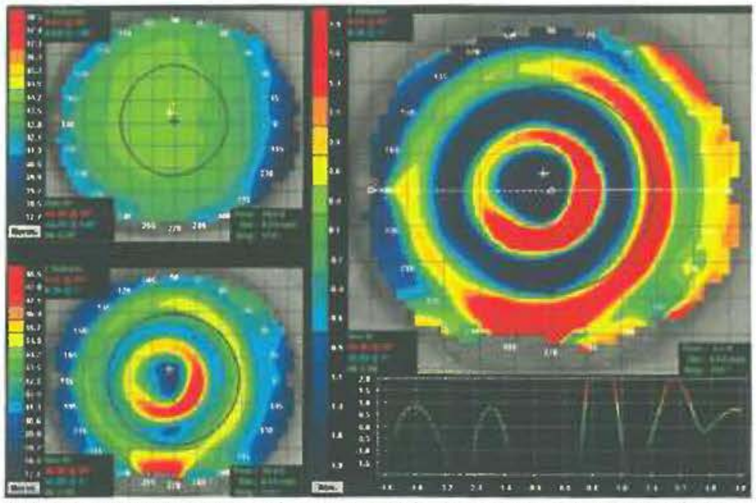
- well centered treatment zone with mid peripheral relief zone
- 0.25mm movement in primary gaze and 0.5mm movement in up gaze
- good limbal coverage
- no flutting
- no bubbles

- unaided VA: 20/20
- Over-refraction: +1.50 D



(Figure 95) OD corneal topographical mapping (after one hour of contact lens wear)

- topographical changes were created
- well centered treatment zone with ring of mid-peripheral steepening and area temporal to center of steepening within treatment zone with adjacent area of nasal flattening
- maximum central flattening: -2.50 D



(Figure 96) OD corneal topographical mapping (after eight hours of contact lens wear)

- topographical changes were created
- well centered treatment zone with ring of mid-peripheral steepening and area temporal to center of steepening within treatment zone with adjacent area of nasal flattening
- maximum central flattening: -5.12 D

Slit lamp examination after eight hour daily wear:

- no contact lens movement
- well-centred
- eye looks white and quiet

Subjective symptoms after eight hours of contact lens wear:

- No foreign body sensation
- Comfortable

Unaided VA: 20/20

10.5 – Anterior Segment OCT High Resolution Corneal Images With Lens In Place

(Figure 97) Anterior Segment Single OD
(after one hour of contact lens wear)

(Figure 98) High Resolution Corneal OD
(after one hour of contact lens wear)

Chapter 11

Appendix A

11.1 Conclusions

Data collected from our pilot studies further supports that soft contact lenses can be used to correct myopia with predictable results during orthokeratology. Furthermore our studies confirmed that reverse geometry lenses are the best design to achieve significant reshaping of the cornea but difference in materials produced similar results. We ascertained that everted lenses create a maximum corneal change of approximately 1.00 D and significant corneal change can occur within the first hour of daily wear. All subjects reported comfort levels inline with standard contact lens wears. Optimal centration was also supported by the pilot study data. Now having achieved predictable corneal reshaping with improved patient comfort and centration our studies identified needed improvement in paracentral steepening to move orthokeratology towards being a viable and reliable treatment of myopia. We need to reduce, or eliminate, the paracentral steepening in the cornea created by the reverse geometry lens. Continued studies at Pacific University should be created to address this undesirable effect.

11.2 Future Design Considerations/Expectations

Future study designs in orthokeratology should address and expand our knowledge on the following considerations:

1. reduce lens thickness to optimize corneal physiology
2. further optimization of lens material
3. comparisons of overnight versus daily wear
4. increased stability of results
5. correction of hyperopia
6. acceptable corrections of correcting astigmatism
7. identify soft contact lens material and manufacturing techniques that provide accurate and consistently repeatable results
8. provide a larger more evenly consistent treatment zone of flattening (Eliminate the mid-peripheral ring of steepening)
9. identify the maximum amount of corneal flattening achievable

Chapter 12

Appendix B

12.1 Acknowledgements

Manufacturers:

- Paragon Vision Science: Mesa, AZ
- MedLens Innovation Inc.: Front Royal, VA

Materials:

- The Lagado Corporation: Englewood, CO
- Benz Research & Development: Sarasota, FL

Premises and required equipment:

- Pacific University College of Optometry: Forest Grove, OR

Intellectual property:

- The University of New South Wales
  School of Optometry and Vision Science: Sydney, Australia
- The Vision Cooperative Research Centre: Sydney. Australia

The following institutions made it possible to perform this thesis project successfully.
Paragon Vision Science (Mesa, AZ) and MedLens Innovation Inc. (Front Royal, VA) manufactured all examined soft contact lenses.
The Lagado Corporation (Englewood, CO) and Benz Research & Development (Sarasota, FL) provided the soft contact lens materials.
Special thanks go to Pacific University College of Optometry (Forest Grove, OR) for the supporting premises and all required equipment.
The whole project was able to be realized through the permission of the University of New South Wales School of Optometry and Vision Science and the Vision Cooperative Research Center which are both located in Sydney, Australia.

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12.3 Literature Research

Database Tools:

Annual Reviews (Biomedical, Physical, and Social Sciences)

ArticleFirst

Alt HealthWatch

BIOSIS Previews

Blackwell Synergy (full-text access to only selected journals)

Cambridge Scientific Abstracts (CSA) Databases

CINAHL (Cumulative Index to Nursing and Allied Health Literature)

Dissertations Abstracts Online

Duane's Ophthalmology (e-book)

ECO (Electronic Collections Online)

Health Source: Academic/Nursing Edition

JAMA & Archives

JSTOR

MEDLINE - OVID

MDConsult

PapersFirst

Project MUSE

Sage Journals Online (Library has full-text access to approximately 430 titles)

ScienceDirect (Library has full-text access to approximately 150 titles)

SpringerLink

Visionet (User ID/Password needed)

Web of Science

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